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August 26, 1992

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Washington, DC 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

Re: CAP Agreement Identification No. 8ECAP-0110

Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following report pursuant to the terms of the TSCA §8(e) Compliance Audit Program and Union Carbide's CAP Agreement dated August 14, 1991 (8ECAP-0110). This report describes A 90-day dietary inclusion study in rats with UC 70480 (O-(1-cyano-2-methylpropyl)-O-ethyl-S-propylphosphorothioate; CASRN [not available]).

"UC 70480: Ninety-Day Dietary Inclusion Study in Rats", Bushy Run Research Center, Project Report 49-11, January 14, 1987.

A complete summary of this report is attached.

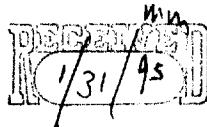
Previous TSCA Section 8(e) or "FYI" Submission(s) related to this substance are:

(None)

Previous PMN submissions related to this substance are: (None)

This information is submitted in light of EPA's current guidance. Union Carbide does not necessarily agree that this information reasonably supports the conclusion that the subject chemical presents a substantial risk of injury to health or the environment.

49-11



(2)

In the attached report the term "CONFIDENTIAL" may appear. This precautionary statement was for internal use at the time of issuance of the report. Confidentiality is hereby waived for purposes of the needs of the Agency in assessing health and safety information. The Agency is advised, however, that the publication rights to the contained information are the property of Union Carbide.

Yours truly,



William C. Kuryla, Ph.D.  
Associate Director  
Product Safety  
(203/794-5230)

WCK/cr

Attachment (3 copies of cover letter, summary, and report)

(3)

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SUMMARY

BUSHY RUN RESEARCH CENTER

R. D. 4, Mellon Road, Export, Pennsylvania 15632

Telephone (412) 733-~~1234~~

PROJECT REPORT  
January 14, 1987

UC 70480 Ninety-Day Dietary Inclusion Study in Rats

Sponsor: Union Carbide Agricultural Products Company

\* \* \* \* \*

SUMMARY

Male and female Sprague-Dawley CD® rats were administered diets containing 0 ppm, 3 ppm, 30 ppm or 300 ppm UC 70480 for 90 days. UC 70480 exposure did not result in mortality in either sex. Depressed body weights and body weight gains were observed throughout the study in 300 ppm male rats. Decreased food intake of 300 ppm male rats paralleled the depression in body weight and body weight gain for this sex. Although overt clinical signs of cholinesterase inhibition were not apparent at any UC 70480 exposure level, biologically significant (greater than 25% of concurrent control values) inhibition of erythrocyte and plasma cholinesterase activity was apparent at weeks 7 and 13 in 30 ppm and 300 ppm male and female rats, and in plasma of 30 ppm female rats. Brain cholinesterase activity was inhibited in the 300 ppm UC 70480 dosage group of both sexes at 13 weeks. Minor decreases in hematocrit and platelets in both sexes as well as in hemoglobin and erythrocyte count in males at the highest dose of UC 70480 were also observed.

CONCLUSIONS

Inhibition of cholinesterase activity (erythrocyte, plasma, brain) and alterations in hematology and clinical chemistry of animals treated with 30 ppm and 300 ppm UC 70480 for 90 days excludes these groups as a no-observable-effect-level (NOEL) for the compound. Based on the information obtained in the present study, dietary concentrations of 3 ppm UC 70480 would appear to be a NOEL for 90 days in male rats and a minimally toxic dose in female rats.



# BUSHY RUN RESEARCH CENTER

R. D. 4, Mellon Road, Export, Pennsylvania 15632

Telephone (412) 733-5200

## Study Title

UC 70480  
Ninety-Day Dietary Inclusion Study in Rats

## Data Requirement

Guidelines 82-3

## Author(s)

J. P. Van Miller, Ph.D.  
D. E. McLain, Ph.D.

## Study Completed On

October 30, 1984

## Performing Laboratory

Bushy Run Research Center  
R. D. #4, Mellon Road  
Export, PA 15632

## Laboratory Project ID

Project Report 49-11

Report Date = 1/14/87

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### Good Laboratory Practices Compliance Statement

This study was conducted in accordance with Good Laboratory Practices Regulations for non-clinical laboratory studies as developed by the Environmental Protection Agency, Pesticides Programs, Good Laboratory Practice Standards, as part of the U. S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), published in the Federal Register, Vol. 48, No. 230, November 29, 1983 (effective May 2, 1984).

Study Director:

John P. Van Miller, Ph.D.  
Bushy Run Research Center

1-7-84

Date

Sponsor:

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\_\_\_\_\_  
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TABLE OF CONTENTS

	<u>Page</u>
GLP Compliance Statement . . . . .	2
List of Tables and Figures . . . . .	4
Summary . . . . .	6
Introduction. . . . .	6
 Materials and Methods	
Test Substance. . . . .	7
Animals and Animal Care . . . . .	7
Diet Preparation and Analysis . . . . .	7
Experimental Design . . . . .	8
Clinical Methodology. . . . .	9
Cholinesterase. . . . .	9
Serum Clinical Chemistry. . . . .	10
Hematology. . . . .	11
Urinalysis. . . . .	11
Experimental Evaluation . . . . .	11
Gross and Histomorphologic Pathology. . . . .	12
Statistical Procedures. . . . .	12
 Results and Discussion	
Pre-Study Information and Quality Control . . . . .	13
Diet Analyses . . . . .	13
Mortality . . . . .	14
Body Weight . . . . .	14
Food Consumption. . . . .	14
Compound Intake . . . . .	15
Clinical Observations. . . . .	15
Hematology. . . . .	15
Cholinesterase. . . . .	15
Clinical Chemistry. . . . .	16
Urinalysis. . . . .	16
Organ Weights . . . . .	16
Gross and Histomorphologic Pathology. . . . .	17
Conclusions . . . . .	17
Signatures. . . . .	17
Acknowledgements. . . . .	18
References. . . . .	19
Tables and Figures. . . . .	20-161
QAU Study Inspection Summary. . . . .	162
 Analytical Chemistry Report - Appendix 1 . . . . .	164-175
Clinical Pathology Record - Appendix 2 . . . . .	176-282
Experimental Toxicology Record - Appendix 3 . . . . .	283-394
Anatomic Pathology Record - Appendix 4 . . . . .	395-671

# BEST COPY AVAILABLE

Report 49-11

## LIST OF TABLES AND FIGURES

<u>Table/Figure</u>	<u>Page</u>
1. In-Life Numbers and Animal Information-Males . . . . .	20
2. In-Life Numbers and Animal Information-Females . . . . .	24
3. Body Weight (G), Summary of Means-Males . . . . .	28
4. Body Weight Gains (G) From Interval Zero, Summary of Means-Males . . . . .	32
F1. Mean Body Weight(G) Versus Time (Weeks)-Males . . . . .	36
5. Body Weight (G) Summary of Means-Females. . . . .	37
6. Body Weight Gains (G) From Interval Zero, Summary of Means-Females . . . . .	41
F2. Mean Body Weight (G) Versus Time (Weeks)-Females. . . . .	45
7. Food Intake (Grams/Animal/Day), Summary of Means-Males. . . . .	46
8. Food Intake (Grams/Animal/Day), Summary of Means-Females. . . . .	57
9. Calculated Dosage of UC 70480 Ingested (Mg/Kg Body Weight/Day) by Male Rats . . . . .	68
10. Calculated Dosage of UC 70480 Ingested (Mg/Kg Body Weight/Day) by Female Rats . . . . .	70
11. Clinical Observations, Summary of Incidence-Males . . . . .	72
12. Clinical Observations, Summary of Incidence-Females . . . . .	73
13. Mean Results of Hematologic Determinations-7-Week Results . . . . .	74
14. Mean Results of Hematologic Determinations-13-Week Results. . . . .	75
15. Mean Results of Hematologic Determinations-17-Week Results. . . . .	76
16. Mean and Median Results of Leukocyte Differentials and Heinz Body Counts-7-Week Results . . . . .	77
17. Mean and Median Results of Leukocyte Differentials and Heinz Body Counts-13-Week Results. . . . .	78
18. Mean and Median Results of Leukocyte Differentials and Heinz Body Counts-17-Week Results. . . . .	79
19. Mean Results of Coagulation Determinations-7-Week Results . . . . .	80
20. Mean Results of Coagulation Determinations-13-Week Results. . . . .	81
21. Mean Results of Coagulation Determinations-17-Week Results. . . . .	82
22. Mean Results of Cholinesterase Determinations-7-Week Results. . . . .	83
23. Mean Results of Cholinesterase Determinations-13-Week Results . . . . .	84
24. Mean Results of Cholinesterase Determinations-17-Week Results . . . . .	85
25. Mean and Median Results of Clinical Chemistry Parameters, Males-7-Week Results . . . . .	86
26. Mean and Median Results of Clinical Chemistry Parameters, Females-7-Week Results . . . . .	87
27. Mean and Median Results of Clinical Chemistry Determinations, Males-13-Week Results. . . . .	88
28. Mean and Median Results of Clinical Chemistry Determinations, Females-13-Week Results. . . . .	89
29. Mean and Median Results of Clinical Chemistry Determinations, 17-Week Results. . . . .	90

# BEST COPY AVAILABLE

Report 49-11

## LIST OF TABLES AND FIGURES (Continued)

<u>Table/Figure</u>	<u>Page</u>
30. Mean and Median Results of Urinalysis Determinations-6-Week Results.	91
31. Results of Urine Microscopics-6-Week Results.	92
32. Mean and Median Results of Urinalysis Determinations-12-Week Results.	93
33. Results of Urine Microscopics-12-Week Results.	94
34. Mean and Median Results of Urinalysis Determinations-16-Week Results.	95
35. Results of Urine Microscopics-16-Week Results.	96
36. Organ Weights (G), Summary of Means, Males-13-Week Results.	97
37. Organ Weights as % of Final Body Weight, Males-13-Week Results.	99
38. Organ Weights as % of Brain Weight, Males-13-Week Results.	101
39. Final Body Weights (G), Summary of Means, Males-13-Week Results.	103
40. Organ Weights (G), Summary of Means, Males-17-Week Results.	104
41. Organ Weights as % of Final Body Weight, Males-17-Week Results.	106
42. Organ Weights as % of Brain Weight, Males-17-Week Results.	108
43. Final Body Weights (G), Summary of Means, Males-17-Week Results.	110
44. Organ Weights (G), Summary of Means, Females-13-Week Results.	111
45. Organ Weights as % of Final Body Weight, Females-13-Week Results.	113
46. Organ Weights as % of Brain Weight, Females-13-Week Results.	115
47. Final Body Weights (G), Summary of Means, Females-13-Week Results.	117
48. Organ Weights (G), Summary of Means, Females-17-Week Results.	118
49. Organ Weights as % of Final Body Weight, Females-17-Week Results.	120
50. Organ Weights as % of Brain Weight, Females-17-Week Results.	122
51. Final Body Weights (G), Summary of Means, Females-17-Week Results.	124
52. Gross Necropsy Observations, Incidence Summary, Males-13-Week Results.	125
53. Gross Necropsy Observations, Incidence Summary, Females 13-Week Results.	126
54. Histomorphological Diagnosis-Incidence Summary, Males-13-Week Results.	127
55. Histomorphological Diagnosis-Incidence Summary, Females-13-Week Results.	135
56. Gross Necropsy Observations, Incidence Summary-Found Dead Animals.	141
57. Histomorphological Observations, Incidence Summary-Found Dead Animals.	142
58. Gross Necropsy Observations-Incidence Summary, Males-17-Week Results.	147
59. Gross Necropsy Observations-Incidence Summary, Females-17-Week Results.	148
60. Histomorphological Diagnosis-Incidence Summary, Males-17-Week Results.	149
61. Histomorphological Diagnosis-Incidence Summary, Females-17-Week Results.	156

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PROJECT REPORT  
January 14, 1987

### UC 70480 Ninety-Day Dietary Inclusion Study in Rats

Sponsor: Union Carbide Agricultural Products Company

\* \* \* \* \*

#### SUMMARY

Male and female Sprague-Dawley CD® rats were administered diets containing 0 ppm, 3 ppm, 30 ppm or 300 ppm UC 70480 for 90 days. UC 70480 exposure did not result in mortality in either sex. Depressed body weights, body weight gains were observed throughout the study in 300 ppm male rats. Decreased food intake of 300 ppm male rats paralleled the depression in body weight and body weight gain for this sex. Although overt clinical signs of cholinesterase inhibition were not apparent at any UC 70480 exposure level, biologically significant (greater than 25% of concurrent control values) inhibition of erythrocyte and plasma cholinesterase activity was apparent weeks 7 and 13 in 30 ppm and 300 ppm male and female rats, and in plasma of 300 ppm female rats. Brain cholinesterase activity was inhibited in the 300 ppm UC 70480 dosage group of both sexes at 13 weeks. Minor decreases in hematocrit and platelets in both sexes as well as in hemoglobin and erythrocyte count in males at the highest dose of UC 70480 were also observed.

#### INTRODUCTION

The purpose of this study was to evaluate any toxic effects in rats due to repeated oral exposure to UC 70480 for 90 days. The oral route is a probable human exposure route. Preliminary range-finding studies of two weeks (BRRC Report No. 47-129) and four weeks duration (BRRC Report No. 47-123) were performed in rats and the results were used to set concentration levels in the study. Since the lowest concentration used in the two-week study, 3 ppm, did not produce systemic toxicity, the lowest concentration of this subchronic study was set at 3 ppm UC 70480.

#### MATERIALS AND METHODS

This study was conducted according to the protocol (BRRC Project No. 84-03-50003) approved by Union Carbide Agricultural Products Company, Inc. The first day rats received UC 70480 was July 2, 1984. The last day of recovery animal sacrifice was October 30, 1984.

Bushy Run Research Center  
A Joint Mellon Institute—Union Carbide Corporation Operation

Test Substance

Approximately 450 g of UC 70480 [0-(1-cyano-2-methylpropyl)-0-ethyl-S-propylphosphorothioate] were received on May 17, 1984 from Union Carbide Agricultural Products Company, Inc. (UCAPC, Research Triangle Park, NC). The sample was labeled with the identification number HTS4820AA and assigned BRRC sample number 47-135 (A,B). The test material was a colorless, slightly viscous, transparent liquid with an analytical purity of 95.77% (analysis provided by sponsor). No CAS Registry number was available for the material. A reserve 20 g sample was taken and stored frozen in Room 164 of the Chemical Hygiene Fellowship (CHF) building at BRRC.

Animals and Animal Care

Two hundred eighty-seven (287) Sprague-Dawley CD® rats (144 males, 143 females), 35 days of age, were received from Charles River Breeding Laboratories, Inc., Kingston, NY on June 18, 1984. Upon receipt, quality control procedures, including blood serology and aerobic bacteriology cultures from the lung, were performed on 5 animals/sex. Examination for parasites was done on feces collected from 6 cages (2 animals/cage). In addition, the liver, lungs, heart, kidneys, salivary glands, trachea, nasal cavity and cervical lymph nodes were fixed and examined microscopically.

All animals were allowed a 2 week environmental acclimation phase before experimental treatment. From receipt to study termination, rats were individually housed in stainless steel wire-mesh cages (9" L x 6" W x 7" H) mounted in stainless steel racks in Room 170 of the CHF building. A layer of Deotized Animal Cage Board® (Shepherd Specialty Papers, Inc., Kalamazoo, MI) was placed under each cage and changed at least three times per week. Other animal care procedures were performed regularly by animal care personnel according to BRRC Standard Operating Procedures. The Guide for Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources, National Research Council, Department of Health, Education and Welfare, Publication No. 78-23, 1978) was followed to provide adequate care for the animals. Water (Municipal Authority of Westmoreland County, Greensburg, PA) was supplied by an automatic dispensing system. A certified ground rodent feed (Purina Certified Rodent Chow #5002, Ralston Purina Company, St. Louis, MO) was provided in 8 oz. opal glass jars. Food and water were available ad libitum. Rats were kept on a 12-hour photoperiod throughout the study. Room temperature ( $22 \pm 3^{\circ}\text{C}$ ) and relative humidity (30-74%) were recorded (Cole-Parmer Hygrothermograph® Seven-Day Continuous Recorder, Model #8368-00). Animals were identified by toe-clipping.

Diet Preparation and Analysis

The basic diet used for diet preparation was ground Purina Certified Rodent Chow #5002 (Ralston Purina Company, St. Louis, MO). Analysis of chemical composition and possible contaminants of each batch of diet were performed by Raltech Scientific Services, St. Louis, MO, and nitrosamine analysis was performed by Hazleton Laboratories Inc., Madison, WI.

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For the actual diet preparation, a solution of UC 70480 dissolved in acetone (10 ml acetone/g UC 70480) was prepared. This solution was then added to ground chow and mixed in a Hobart mixer to produce a 3000 ppm (w/w) premix. Mixing time was approximately thirty minutes to allow enough time for complete acetone evaporation. To insure homogeneity at the lower dosage levels, this initial premix was used to prepare the highest dosage level and a second premix of 100 ppm. The 100 ppm premix was then used to prepare the intermediate and low dosage levels. In all cases, the individual test diets were prepared by adding the appropriate amount of premix to ground diet and mixing in a Hobart mixer for approximately 15 minutes. Control diets were prepared from a premix containing acetone concentrations to yield equivalent amounts of control vehicle as in the high dose group diet after proper dilution. Both premixes and all test diets were prepared weekly on the same day. Test diets were stored at -20°C except during designated feeding times. Animals were fed 3 times weekly.

Homogeneity, stability, and analysis of test diets for concentrations of UC 70480 were performed at BRRC.

### Experimental Design

The dosage levels of UC 70480 were selected based on preliminary findings from a two-week and four-week dietary inclusion study of UC 70480 performed at BRRC. The experimental design is summarized in the following table:

Exposure Levels for UC 70480 90-Day Dietary Inclusion Study in Rats

Group	Exposure Levels (ppm in Diet)	Number of Rats
		Male
		Female
-	0.0 (Predose Control)	10
1	0.0 (Control)	30
2	3	20
3	30	20
4	300	30

Ten animals/sex (predose control group) were used to establish the general health of the test population (e.g. clinical pathology) and then sacrificed and discarded immediately prior to study initiation. Predose animals were selected from the extra animals after computer randomization into study groups. Twenty animals/sex were subdivided by computer randomization as follows; 10 animals/sex/group were designated for hematology, coagulation tests and methemoglobin determination at weeks 7 and 13; and 10 animals/sex/group were designated for clinical chemistry and cholinesterase at weeks 7 and 13. Ten animals/sex in groups 1 and 4 were placed on control diet for one month at 13 weeks to serve as recovery groups.

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Animals selected for clinical pathology and cholinesterase assays at 7 weeks were also used for these assays at 13 weeks. Animals selected for hematolgy, coagulation tests, and methemoglobin determinations at 7 weeks were used for these assays at 13 weeks.

Rats were assigned to groups using a computer-generated statistical randomization procedure. Rats judged unsuitable for study because of abnormal clinical signs or body weights (weights greater than  $\pm 2$  SD from the mean for that sex) and those left after all study groups had been filled were removed from the study and their fate documented. The means and variances of the body weights for all groups were statistically equivalent before dosing was initiated. Body weight ranges at dosage initiation were 201-236 g for males and 149-180 g for females.

To accommodate the number of blood samples to be collected and processed during the study and at termination, male and female rats began treatment one week apart (July 2-3, 1984) and collection of blood samples was staggered over a 4-day period. To achieve a balanced design, one-half of each sex per group were randomly designated for blood collection on days 1 and 3 (males) and 2 and 4 (females) of each 4 day sampling period.

Ophthalmic examinations were performed on all animals prior to study initiation using an indirect ophthalmoscope. Those with unsuitable lesions were discarded and replaced. These examinations were repeated prior to the day sacrifice.

## Clinical Methodology

Blood samples for clinical pathology analyses were collected by orbital bleeding of animals fasted overnight. One set of 10 animals per group per sex were bled for the following analyses: hematolgy, methemoglobin, and coagulation analyses. Another set, also 10 animals per group per sex, were bled for clinical chemistry and cholinesterase determinations. After a 4-week recovery period, samples for hematolgy, methemoglobin, coagulation, clinical chemistry, cholinesterase and urinalysis were collected from 10 animals per sex per group from the 300 ppm UC 70480 group (recovery) and from the control group.

## Cholinesterase

Samples for erythrocyte and plasma cholinesterase were obtained from animals fasted overnight prior to dosing, at 7 and 13 weeks, and following a 4-week recovery period. Samples for brain cholinesterase were obtained at 13 weeks and following the 4-week recovery period. Approximately 2.0 ml of blood were collected into tubes with sodium heparin as anticoagulant (Vacutainer® brand, Becton-Dickinson Company, Rutherford, NJ). Plasma was separated from clotted blood cells by centrifugation prior to assay.

Brains were homogenized utilizing a Polytron® tissue homogenizer (Polytron Kinematics, Luzern, Switzerland). The homogenate was centrifuged and supernatant analyzed for brain cholinesterase activity.

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Cholinesterase assays were performed on an Auto-Analyzer II C equipped with data handler (Technicon Instrument Corporation, Tarrytown, NY) and teletype printer (Teletype Corporation, Skokie, IL). Commercially available control samples (Decision Level 1, Level 2, Level 3, Beckman Instruments, Inc., Clinical Instruments Division, Fullerton, CA) were assayed immediately prior to and following each group of erythrocyte, plasma, and brain samples. All cholinesterase assays were performed on the day of sample collection.

## Serum Clinical Chemistry

Blood samples for serum chemistry analyses prior to dosing and at 7, 13, and 17 weeks were also collected from rats fasted overnight. Approximately 1.0 ml of blood was collected into tubes without anticoagulant (Vacutainer® Brand, Becton-Dickinson Company, Rutherford, NJ).

The following chemistry analyses were performed at 7 and 13 weeks and following a 4-week recovery period:

- |                               |                                    |
|-------------------------------|------------------------------------|
| 1. glucose                    | 11. lactic dehydrogenase           |
| 2. urea nitrogen              | 12. $\gamma$ -glutamyl transferase |
| 3. aspartate aminotransferase | 13. cholesterol                    |
| 4. alanine aminotransferase   | 14. alkaline phosphatase           |
| 5. total protein              | 15. calcium                        |
| 6. albumin                    | 16. inorganic phosphorus           |
| 7. globulin                   | 17. sodium                         |
| 8. A/G ratio                  | 18. potassium                      |
| 9. total bilirubin            | 19. chloride                       |
| 10. creatinine phosphokinase  |                                    |

The Astra™-8 or Astra™-4 Automated Stat/Routine Analyzer (Beckman Instruments, Inc., Brea, CA) was used to analyze serum concentrations of glucose, urea nitrogen, total bilirubin, sodium, potassium, and chloride. Serum controls (Decision Level 1, Level 2, Level 3, Beckman Instruments, Inc., Clinical Instruments Division, Fullerton, CA) were analyzed after each 10 samples. Calibration checks were made immediately prior to sample analyses.

The CentrifilChem® centrifugal analyzer (Baker Instruments, Pleasantville, NY) was used to analyze serum concentrations of aspartate aminotransferase, alanine aminotransferase, creatinine phosphokinase, lactic dehydrogenase,  $\gamma$ -glutamyl transferase, cholesterol, alkaline phosphatase, calcium, inorganic phosphorus, total protein, and albumin. Globulin, the difference between total protein and albumin, and albumin to globulin ratio were calculated. Serum controls (Decision Level 1, Level 2, Level 3, Beckman Instruments, Inc., Clinical Instruments Division, Fullerton, CA) were assayed with each run of 20 samples. Precision checks were made on this instrument in the week immediately preceding the day of sample analysis. All serum clinical chemistry analyses were performed on the day of sample collection.

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## Hematology

Samples for hematologic determinations were also obtained from rats fasted overnight prior to dosing and at 7, 13, and 17 weeks. Approximately 1.0 ml of blood was collected into each of two tubes containing EDTA as an anticoagulant (Vacutainer® Brand, Becton-Dickinson Company, Rutherford, NJ).

The following hematologic parameters were measured: total leukocyte count, erythrocyte count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, and platelet count. Blood smears for differential leukocyte counts and Heinz body counts were prepared and evaluated for all animals. Reticulocyte and bone marrow smears were prepared for each animal but not evaluated.

Hematologic analyses, with the exception of differential leukocyte and Heinz Body counts, were performed on a Coulter Counter® S-Plus IV (Coulter Electronics, Inc., Hialeah, FL). Commercially available quality control samples (4C Plus II Coulter Counter Cell Control, Coulter Diagnostics, Hialeah, FL) were analyzed prior to the samples. All hematologic analyses, other than the differential leukocyte and Heinz Body counts, were performed on the day of sample collection.

Methemoglobin analyses were performed on the Beckman Trace™ III Chemistry System (Beckman Instruments, Inc., Fullerton, CA). Wavelength calibration and photometric accuracy evaluation was performed daily prior to sample analyses.

Approximately 0.5 ml of blood was collected into each of two tubes containing sodium citrate as anticoagulant (Vacutainer® Brand, Becton-Dickinson Company, Rutherford, NJ). The analysis of prothrombin time and partial thromboplastin time were performed on the BBL Fibrometer (Becton-Dickinson Company, Rutherford, NJ). Commercially available coagulation control samples (Ortho Diagnostic Systems, Inc., Raritan, NJ) were assayed with the samples.

## Urinalysis

Samples for urinalysis were obtained prior to dosing and at 6, 12, and 16 weeks. Urine volume was measured using calibrated test tubes, and urine color and turbidity were visually assessed. Urine specific gravity was determined by refractometry using a clinical refractometer (American Optical Co, Buffalo, NY). Semiquantitative measurements were made on urine pH, protein, glucose, ketone, bilirubin, blood, and urobilinogen using the Ames Multi-stix® Reagent Strip and read on the Clini-tek® (Ames Division, Miles Laboratories, Elkhart, IN). Microscopic constituents in the urine were analyzed using the KOVA® System. Appropriate commercially available controls and Clini-tek® Performance capsules were analyzed on each day of urinalysis.

## Experimental Evaluation

Body Weights: Body weights and body weight gains were measured weekly for all animals.

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**Food Consumption:** Fresh diet was offered, and consumption measured, three times each week (Monday, Wednesday, and Friday).

**Mortality Checks:** Mortality checks were performed twice daily (a.m., p.m.) on weekdays and once daily (a.m.) on weekends.

**Clinical Observations:** Observations for overt clinical signs of UC 70480 toxicity were made once daily on weekdays.

## Gross and Histomorphologic Pathology

**Animal Sacrifice and Necropsy:** All animals found dead in the cage or sacrificed at either 13 or 17 weeks were subjected to a detailed macroscopic examination. In addition, the brain, liver, kidneys, heart, spleen, adrenals, and gonads (ovaries/testes) were removed and weighed from sacrificed animals only. Animals were killed from exsanguination by severing the brachial blood vessels following anesthetization with methoxyflurane for retroorbital blood sampling. Final body weights were obtained the day of sacrifice on fasted animals.

**Histopathology:** Appropriate samples of tissues from all animals were preserved in 10% neutral buffered formalin for histopathologic examination. Histopathologic examinations were performed on the following tissues and organs from all animals in the control and high dose groups at final sacrifice and at the recovery sacrifice, and from all animals that died during the study: Tumors (and associated tissues), gross lesions (with adjacent tissue), brain (cerebrum, cerebellum, brainstem), spinal cord (three levels), eyes, pituitary, salivary glands, heart, thymus, thyroid (with parathyroid), lungs (with mainstem bronchi), trachea, spleen, sternum or femur (with marrow), lymph nodes (2, mandibular and mesenteric), sciatic nerve, esophagus, stomach (cardia, fundus and pylorus), duodenum, jejunum, ileum, cecum, colon, rectum, adrenal, pancreas, liver (at least two lobes), kidneys, urinary bladder, ovaries/testes, prostate, epididymis, vagina, uterus/cervix, skin, mammary gland area, and skeletal muscle. In addition, all gross lesions, tumors, lungs, liver, kidneys and all organs and tissues showing evidence of lesions in the high dose group (target organ) were examined for all animals in the low and intermediate dose groups. Deviations from this list are described in the Anatomic Pathology Record (Appendix 4).

## Statistical Procedures

Body weight and food consumption, as well as the data for the organ weights, hematology, clinical chemistry, and cholinesterase determinations from the four groups were intercompared using Levene's test for homogeneity of variance<sup>1</sup>. An analysis of variance<sup>2</sup> was performed on the groups with homogeneous variances and, if found to be significant, group differences were delineated by grouped variance Student t-tests<sup>3</sup>. When heterogeneous variances were indicated, Welch and Brown-Forsythe<sup>4</sup> analyses were performed. If either was significant, group differences were determined by separate variance Student t-tests<sup>3</sup>.

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Report 49-11

Medians<sup>5</sup> and quartile deviations<sup>5</sup> were calculated for non-parametric data. These data were statistically analyzed by the Kruskal-Wallis test<sup>6</sup> or by the Wilcoxon rank sum test as modified by Mann-Whitney<sup>7</sup>. The fiducial limit of 0.05 (2-tailed) was used as the critical level of significance for all tests.

## Storage of Records

The final report, nonperishable specimens, and all raw data are retained in the Archives of the Bushy Run Research Center.

## RESULTS AND DISCUSSION

### Pre-Study Information and Quality Control

The 144 male and 143 female rats arrived at BRRC on June 18, 1984. The birth date of the animals was recorded as May 14, 1984.

Results of quality control evaluations, including serology, parasitology, histology and physical examination, were within normal limits established from data for historical controls. Ophthalmic examinations performed on these animals revealed no significant lesions upon receipt.

Feed contaminant analyses, supplied by the Ralston Purina Co. Central Research Services (St. Louis, MO) for all feed lots used in the study indicated all contaminants were within the acceptable levels. Assays of feed lots used (supplied by Hazleton Laboratories, Inc., Madison, WI) indicated nitrosamine concentrations were within acceptable range. Water analysis was conducted by the Municipal Authority of Westmoreland County (MAWC) on a water sample collected at BRRC in the summer of 1984. None of the EPA standards for maximum levels of contaminants were exceeded. Furthermore, no notable differences were evident between contaminant levels reported in BRRC water in previous years and the present analysis.

On June 27, 1984 predose blood and urine samples were obtained from ten male and ten female rats. Samples were submitted to Clinical Pathology for all analyses listed in the study protocol (i.e., hematology, coagulation, clinical chemistry, cholinesterase, and urinalysis). Samples for coagulation and methemoglobin were not evaluated because of problems with the analyses. All other available results from this predose sampling period were tabulated, evaluated, and found to be within the historical normal range for 6-week old Sprague-Dawley rats in this laboratory.

### Diet Analyses

A complete Analytical Chemistry Report, including Summary, Introduction, Materials and Methods, and Results, is included in Appendix 1.

The stability study of UC 70480 in rodent diet showed that at frozen conditions, the 3 ppm diet mixtures remained stable for 7 days, and the 300 ppm test diet remained stable for 21 days (Table 2, Appendix 1). Based on these results, test diets were prepared weekly, stored frozen, and fed three times weekly.

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Report 45

The homogeneity study indicated that the distribution of UC 70480 in test diet was uniform (Table 3, Appendix 1). In addition, the periodic analysis of the concentration of UC 70480 in the test diet showed good agreement between the expected and actual values throughout the study (Table 3, Appendix 1).

## Mortality

Detailed records of individual animal fate by group are reported in Tables 7 and 8 of Appendix 3 (Experimental Toxicology Record, In-Life Numbers and Animal Information). UC 70480 dietary concentrations of 3, 30, or 300 ppm did not result in mortality in either sex of rats. Four females (1 control, 5 mid-dose, and 2 high dose) died as a result of blood sampling procedures during the 7-week evaluation period.

## Body Weight

Body weights and body weight gains of male rats are reported in Table 4, respectively. A graph of male body weight versus time (days) is shown in Figure 1. Body weights and body weight gains of female rats are reported in Table 5 and Table 6, respectively. A graph of female body weight versus time (days) is shown in Figure 2. Individual body weights are reported in Appendix 3.

Depressed body weight (weeks 1-13) and body weight gain from day zero (weeks 1-13) were apparent in male rats consuming 300 ppm UC 70480. However, absolute body weight differences did not exceed 6% of concurrent controls. During the recovery period (weeks 14-17) high-dose male rats fed control diet gained approximately 31% more weight (64 g) than concurrent controls (44 g).

No statistical difference in absolute body weight was apparent in female rats consuming 300 ppm UC 70480. However, body weight gain from day zero was significantly depressed through study week 4 and at week 6. These differences (15-20% of concurrent controls) were not statistically significant after study week 6.

## Food Consumption

Food intake for 300 ppm UC 70480 male rats (Table 7) was statistically less than controls for food measurement days 2, 4, 25, 35, and 39. In contrast, during the recovery period high dose males fed control diet consumed significantly more food than controls on days 93, 95, 100 and 107.

For 300 ppm female rats, food intake was significantly less than controls for food measurement days 1, 3, 10, 13, 15, 20, 27, 36 and 66 (Table 8). However, with the exception of day 92, no compensatory increase was apparent during the recovery period.

Individual food intake records for male and female rats are reported in Appendix 3.

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Report 49-11

## Compound Intake

UC 70480 intake (mg/kg body weight/day) by male and female rats is reported in Table 9 and Table 10, respectively. Mean dosages attained by 3, 30, and 300 ppm UC 70480-treated male rats were 0.2, 2.0, and 19.7 mg/kg/day, respectively. Corresponding values for female rats were 0.2, 2.3 and 22.9 mg/kg/day, respectively.

## Clinical Observations

No treatment-related effect on the incidence of clinical signs (Tables 11-12) was apparent at any dose in either sex. A chronological list of individual examination findings is included in Appendix 3.

## Hematology

The mean results of hematologic determinations and coagulation function at 7, 13, and 17 weeks for male and female rats exposed to UC 70480 are reported in Tables 13-21. Individual results for these determinations are included in Appendix 2.

A slight decrease (approximately 3%) in hematocrit was observed in male rats from the 300 ppm group at week 7. A larger reduction (approximately 7%) in hematocrit was observed in these animals at 13 weeks, and this change was accompanied by moderate reductions in hemoglobin and erythrocyte count. A decrease in hematocrit of the females from the 300 ppm group was also observed at 13 weeks. The decrease in hematocrit observed at 7 weeks in the 3 ppm male group was considered unrelated to UC 70480 exposure based on the lack of dose response and the lack of consistency in the 13-week measurement. No differences were seen in these parameters after the 4-week recovery period.

The platelet count (Plt) was significantly increased in male rats at 7 weeks (30 ppm, 300 ppm) and 13 weeks (300 ppm), and in female rats at 7 weeks (300 ppm). Leukocyte counts (WBC) were also increased in 300 ppm female rats at 7 weeks due to increased levels of lymphocytes and monocytes. Other statistically significant alterations were considered spurious or of equivocal biological importance. The statistically significant increase in methemoglobin (Mhgb) level of 300 ppm male rats at week 17 was considered spurious since no alterations in Mhgb were observed during the dosing phase of the study.

No biologically significant alterations were observed in the analysis of coagulation function (Tables 19-21). Statistically significant decreases in partial thromboplastin time (PTT) at 7 weeks were considered spurious due to lack of dose-response and the lack of consistency at the 13-week measurement.

## Cholinesterase

The mean results and percent inhibition of the cholinesterase determinations at 7, 13 and 17 weeks for male and female rats exposed to UC 70480 are reported in Tables 22-24, respectively. Individual results for these determinations are reported in Appendix 2.

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Report 49-11

A biologically significant cholinesterase inhibition (greater than 25% of concurrent control values) was observed in plasma and erythrocytes of 30 ppm and 300 ppm male and female rats, and in plasma of 3 ppm female rats at study weeks 7 and 13. In addition, brain cholinesterase activity was inhibited in the 300 ppm dosage group of both sexes at the 13-week measurement (Table 23). No differences were detected in plasma, erythrocyte, or brain cholinesterase levels of recovery animals sacrificed at week 17 (Table 24).

## Clinical Chemistry

The mean results of clinical chemistry determinations at 7, 13, and 17 weeks for male and female rats exposed to UC 70480 are reported in Tables 25-29. Individual results for these determinations are reported in Appendix 2.

A statistically significant decrease in serum glucose was observed at 7 weeks in male rats of the 300 ppm UC 70480 dosage group (Table 25). This alteration, approximately 10% as compared to concurrent controls, was not observed at the 13 or 17 week evaluation periods (Tables 27 and 29).

Statistically significant decreases were also observed in total protein, albumin, and globulin of 300 ppm male rats at the 7 and 13 week evaluation periods. Albumin to globulin ratio (A/G) was significantly increased in these animals at 13 weeks reflecting the greater decrease in globulin with respect to albumin concentration. Both globulin and A/G ratio remained significantly altered at the 17 week recovery evaluation while albumin was significantly increased at this period. At the 7 and 13 week evaluation periods, significant decreases were observed in total protein and globulin concentration of the 300 ppm females (Tables 26 and 28). A/G ratio was also increased at these evaluation periods. No effects were observed for females at the 17-week period.

Potassium concentration was also significantly increased in high dose males at 7 weeks and in high dose females at 13 weeks. These alterations are generally without biological significance in the absence of other changes in electrolytes. Increased serum cholesterol noted for male rats at 7 weeks was considered a spurious finding. ALT was decreased in high dose females at 13 weeks but this was not considered biologically significant based on the small magnitude of the change. No alterations were observed for male or female rats in any other clinical chemistry parameters at other evaluation periods.

## Urinalysis

No statistically significant alterations were observed in any urinalysis parameter monitored at 6, 12 or 16 weeks in either male or female rats. The mean results of urinalysis parameters are reported in Tables 30-35. Individual results of these determinations are reported in Appendix 2.

## Organ Weights

Absolute organ weights, organ weights relative to final body weight, organ weights relative to brain weight, and final body weight of male rats are reported in Tables 36-43, respectively. Corresponding values for females are reported in Tables 44-51. Individual organ weights, organ/body and organ/brain weight ratios are reported in Appendix 3.

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Report 49-11

Dietary administration of UC 70480 for 90 days to male or female rats did not result in biologically significant absolute or relative organ weight effects. Apparent absolute organ weight effects in both sexes were due to reduced final body weights at 13 weeks and were not apparent in recovery animals.

## Gross and Histomorphologic Pathology

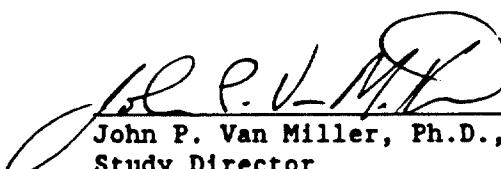
Incidence summaries of gross necropsy and microscopic observations (in-life deaths and final sacrifice) for male and female rats are reported in Tables 52-61. Individual gross and histomorphologic pathology records are included in Appendix 4.

No significant treatment-related pathologic alterations were apparent at gross or microscopic examination of animals dying during the in-life portion of this study or at sacrifice. In addition, no lesions were observed to explain findings of abnormal organ weights. Mild to moderate hydronephrosis was observed in 22 rats (7 males and 15 females) but was not treatment related. This lesion has been described in various rat strains in incidences up to 59% and is considered a spontaneous disease of unknown etiology.<sup>9-12</sup>

## CONCLUSIONS

Inhibition of cholinesterase activity (erythrocyte, plasma, brain) and alterations in hematology and clinical chemistry of animals treated with 30 ppm and 300 ppm UC 70480 for 90 days excludes these groups as a no-observable-effect-level (NOEL) for the compound. Based on the information obtained in the present study, dietary concentrations of 3 ppm UC 70480 would appear to be a NOEL for 90 days in male rats and a minimally toxic dose in female rats.

Reviewed and Approved by:

  
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1-7-87

  
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Report 49-11

## Acknowledgements

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Report 49-11

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11-20-86

TABLE 1  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DAYS ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11041	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11043	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11047	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11048	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11049	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11076	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11079	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11081	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	29-OCT-84	119
11094	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	1-OCT-84	91
11095	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11097	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11099	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	3-OCT-84	93
11104	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	29-OCT-84	119
11113	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11116	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11117	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	1-OCT-84	91
11120	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11122	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11128	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	93	1-OCT-84	93
11136	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11144	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11146	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11149	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11150	M	GROUP P (0 PPM)	SCH SAC	20	3-OCT-84	93	1-OCT-84	91
11155	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	3-OCT-84	93
11158	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	1-OCT-84	91
11162	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11165	M	GROUP P (0 PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11166	M	GROUP P (0 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11176	M	GROUP P (0 PPM)	SCH SAC	24	3-OCT-84	93	3-OCT-84	93
					29-OCT-84	119	29-OCT-84	119

SCH SAC = SCHEDULED SACRIFICE  
M = MALE

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TABLE 1 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DAYS ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11053	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11063	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11066	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11068	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11071	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11072	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11082	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11090	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11091	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11108	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11110	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11123	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11167	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11134	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11142	M GROUP S (3 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11152	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11172	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11174	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11175	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11115	M GROUP S (3 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11044	M GROUP T (30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11045	M GROUP T (30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11050	M GROUP T (30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11057	M GROUP T (30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11064	M GROUP T (30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11073	M GROUP T (30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11083	M GROUP T (30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11092	M GROUP T (30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11100	M GROUP T (30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93

SCH SAC = SCHEDULED SACRIFICE  
M = MALE

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TABLE 1 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DAYS ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11101	M	GROUP T	(30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11119	M	GROUP T	(30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11125	M	GROUP T	(30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11135	M	GROUP T	(30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11143	M	GROUP T	(30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11151	M	GROUP T	(30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11153	M	GROUP T	(30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11157	M	GROUP T	(30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11163	M	GROUP T	(30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11169	M	GROUP T	(30 PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11173	M	GROUP T	(30 PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11046	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84
11054	M	GROUP Y	(300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11058	M	GROUP Y	(300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11059	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84
11062	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84
11065	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84
11069	M	GROUP Y	(300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11074	M	GROUP Y	(300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11075	M	GROUP Y	(300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11085	M	GROUP Y	(300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11086	M	GROUP Y	(300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11089	M	GROUP Y	(300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11093	M	GROUP Y	(300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11102	M	GROUP Y	(300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84
11103	M	GROUP Y	(300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84
11105	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84
11178	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84
11121	M	GROUP Y	(300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84

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 M = MALE

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TABLE 1 (continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DAYS ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11126	M	GROUP Y (300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11131	M	GROUP Y (300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11140	M	GROUP Y (300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11141	M	GROUP Y (300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11145	M	GROUP Y (300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11147	M	GROUP Y (300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11080	M	GROUP Y (300PPM)	SCH SAC	20	1-OCT-84	91	1-OCT-84	91
11161	M	GROUP Y (300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11130	M	GROUP Y (300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11168	M	GROUP Y (300PPM)	SCH SAC	24	29-OCT-84	119	29-OCT-84	119
11170	M	GROUP Y (300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93
11171	M	GROUP Y (300PPM)	SCH SAC	20	3-OCT-84	93	3-OCT-84	93

SCH SAC = SCHEDULED SACRIFICE  
M = MALE

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Report 49

TABLE 2  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DATE ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11188 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11195 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11196 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11198 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11202 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11203 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11206 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11207 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11218 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11219 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11220 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11222 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11240 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11250 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	91	2-OCT-84	91
11252 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	119	30-OCT-84	119
11255 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	91	2-OCT-84	91
11256 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11271 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11272 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	4-OCT-84	93
11274 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11284 F	GROUP P (0 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11288 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11291 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	91	2-OCT-84	91
11292 F	GROUP P (0 PPM)	SCH SAC	24	14-AUG-84	119	30-OCT-84	119
11295 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	42	14-AUG-84	42
11302 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11305 F	GROUP P (0 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11307 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11318 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11320 F	GROUP P (0 PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119

SCH SAC = SCHEDULED SACRIFICE

F = FEMALE

\* = DIED FROM BLEEDING PROCEDURES

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TABLE 2 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DATE ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11194 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11204 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11208 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11214 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11215 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11227 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11238 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11239 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11241 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11244 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11251 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11263 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11275 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11281 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11197 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11293 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11306 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11313 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11315 F	GROUP S (3 PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11319 F	GROUP S (3 PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11187 F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11233 F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11242 F	GROUP T (30PPM)	FD DEAD*	13	16-AUG-84	44	16-AUG-84	44
11253 F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11257 F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11259 F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11261 F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11262 F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	4-OCT-84	91
11265 F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93

SCH SAC = SCHEDULED SACRIFICE

F = FEMALE

\* = DIED FROM BLEEDING PROCEDURES

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TABLE 2 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DATE ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11270	F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11279	F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11286	F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11296	F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11298	F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11301	F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11303	F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11310	F	GROUP T (30PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11314	F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11316	F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11317	F	GROUP T (30PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11190	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11200	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11210	F	GROUP Y (300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11213	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11216	F	GROUP Y (300PPM)	FD DEAD*	13	14-AUG-84	42	14-AUG-84	42
11217	F	GROUP Y (300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11221	F	GROUP Y (300PPM)	FD DEAD*	13	14-AUG-84	42	14-AUG-84	42
11223	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11224	F	GROUP Y (300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11226	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11229	F	GROUP Y (300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11231	F	GROUP Y (300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11237	F	GROUP Y (300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11243	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11246	F	GROUP Y (300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119
11247	F	GROUP Y (300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93
11254	F	GROUP Y (300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91
11264	F	GROUP Y (300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93

SCH SAC = SCHEDULED SACRIFICE

F = FEMALE

\* = DIED FROM BLEEDING PROCEDURES

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TABLE 2 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 IN-LIFE NUMBERS AND ANIMAL INFORMATION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS	DATE OF DEATH	AGE IN WEEKS	DATE OF DEATH	DAYS ON STUDY	DATE OF NECROPSY	DAYS TO NECROPSY
11267	F	GROUP Y	(300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91	
11268	F	GROUP Y	(300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91	
11269	F	GROUP Y	(300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119	
11273	F	GROUP Y	(300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119	
11280	F	GROUP Y	(300PPM)	SCH SAC	24	30-OCT-84	119	30-OCT-84	119	
11282	F	GROUP Y	(300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93	
11283	F	GROUP Y	(300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93	
11290	F	GROUP Y	(300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91	
11294	F	GROUP Y	(300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91	
11299	F	GROUP Y	(300PPM)	SCH SAC	20	2-OCT-84	91	2-OCT-84	91	
11309	F	GROUP Y	(300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93	
11321	F	GROUP Y	(300PPM)	SCH SAC	20	4-OCT-84	93	4-OCT-84	93	

SCH SAC = SCHEDULED SACRIFICE

F = FEMALE

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TABLE 3  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT (G). SUMMARY OF MEANS  
MALES

GROUP (PPM):	0			3			30			300			
	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	
WEEK 0	215.0	7.91	30	215.6	7.74	20	215.0	5.84	20	215.7	8.19	30	
1	MEAN	269.1	13.47	30	272.7	9.70	20	268.0	12.58	20	256.1**	12.98	30
2	MEAN	308.2	18.31	30	311.5	12.17	20	309.1	20.23	20	291.2**	17.85	30
3	MEAN	340.8	21.20	30	345.4	14.49	20	342.8	26.69	20	320.7**	20.68	30

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 3 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT (G). SUMMARY OF MEANS  
 MALES

GROUP (PPM):		0			3			30			300		
WEEK	4	MEAN	370.4	377.8	371.5	348.2**	31.28	31.28	31.28	31.28	31.28	31.28	31.28
		S.D.	24.18	16.05	31.72	23.72	20	20	20	20	20	20	20
	5	MEAN	393.0	401.0	394.7	368.6**	36.17	36.17	36.17	36.17	36.17	36.17	36.17
		S.D.	26.22	18.55	36.17	25.38	20	20	20	20	20	20	20
	6	MEAN	413.1	423.0	417.0	388.0**	39.87	39.87	39.87	39.87	39.87	39.87	39.87
		S.D.	29.48	19.65	36.05	26.05	20	20	20	20	20	20	20
	7	MEAN	420.8	430.9	424.6	401.1*	42.53	42.53	42.53	42.53	42.53	42.53	42.53
		S.D.	34.44	20.21	30.34	30.34	20	20	20	20	20	20	20
	8	MEAN	442.0	453.6	445.9	417.4**	46.54	46.54	46.54	46.54	46.54	46.54	46.54
		S.D.	35.69	23.05	33.28	33.28	20	20	20	20	20	20	20

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
 \*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 3 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT (G), SUMMARY OF MEANS  
 MALES

GROUP (PPM):		0			3			30			300		
WEEK	9	MEAN	457.8	470.0	475.7	488.4	500.6	506.2	500.6	468.7*			
		S.D.	37.14	24.22	25.21	26.04	26.14	27.59	58.30	58.30			
		N	30	20	20	20	20	20	20	20			
10		MEAN	470.0	481.7	475.7	488.4	500.6	506.2	500.6	468.7*			
		S.D.	37.55	25.80	54.80	56.74	57.49	57.49	57.49	57.49			
		N	30	20	20	20	20	20	20	20			
11		MEAN	479.5	492.2	488.4	492.2	494.9	494.9	494.9	494.9			
		S.D.	39.93	26.04	56.74	56.74	57.49	57.49	57.49	57.49			
		N	30	20	20	20	20	20	20	20			
12		MEAN	487.5	500.8	494.9	500.8	500.6	506.2	500.6	468.7*			
		S.D.	40.69	26.14	57.49	57.49	57.49	57.49	57.49	57.49			
		N	30	20	20	20	20	20	20	20			
13		MEAN	492.7	506.2	506.2	506.2	500.6	500.6	500.6	468.7*			
		S.D.	41.04	27.59	27.59	27.59	27.59	27.59	27.59	27.59			
		N	30	20	20	20	20	20	20	20			

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
 \*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 3 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT (G). SUMMARY OF MEANS  
 MALES

GROUP (PPM) :		0			3			30			300		
WEEK	14	MEAN	521.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	507.4	
		S.D.	54.84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	42.18	
		N	10	0	0	0	0	0	0	0	0	10	
15		MEAN	527.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	519.7	
		S.D.	55.17	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	45.01	
		N	10	0	0	0	0	0	0	0	0	10	
16		MEAN	523.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	515.6	
		S.D.	53.73	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	46.64	
		N	10	0	0	0	0	0	0	0	0	10	
17		MEAN	536.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	532.9	
		S.D.	53.44	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	48.62	
		N	10	0	0	0	0	0	0	0	0	10	

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 4  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT GAINS (G) FROM INTERVAL 0, SUMMARY OF MEANS  
MALES

GROUP (PPM):		0			3			30			300		
WEEK	0 TO 1	MEAN	54.1	57.1	53.0	40.4**							
		S.D.	7.15	5.19	8.41	8.04							
		N	30	20	20	30							
0 TO 2	MEAN		93.2	95.9	94.2	75.4**							
	S.D.		12.49	8.95	16.02	14.06							
	N		30	20	20	30							
0 TO 3	MEAN		125.6	129.8	127.8	105.0**							
	S.D.		15.79	12.76	22.46	17.47							
	N		30	20	20	30							
0 TO 4	MEAN		155.4	162.2	156.5	132.5**							
	S.D.		19.15	14.42	27.22	20.01							
	N		30	20	20	30							
0 TO 5	MEAN		178.0	185.4	179.7	152.8**							
	S.D.		21.46	16.82	32.24	21.23							
	N		30	20	20	30							

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 4 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT GAINS (G) FROM INTERVAL 0, SUMMARY OF MEANS  
 MALES

GROUP (PPM):		0			3			30			300		
WEEK	0 TO 6	MEAN	198.1		207.4			202.1			172.3**		
		S.D.	24.66	N	18.35			36.06			21.96		
			30		20			20			30		
0 TO 7	MEAN	205.8			215.3			209.6			185.3**		
	S.D.	30.51		N	19.47			38.70			25.65		
		30			20			20			30		
0 TO 8	MEAN	226.9			237.9			230.9			201.7**		
	S.D.	31.92		N	21.98			42.70			28.97		
		30			20			20			30		
0 TO 9	MEAN	242.8			254.4			245.6			215.6**		
	S.D.	32.90		N	23.63			45.74			29.24		
		30			20			20			30		
0 TO 10	MEAN	255.0			266.1			260.7			229.2**		
	S.D.	33.47		N	24.74			51.32			30.97		
		30			20			20			30		

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 4 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT GAINS (G) FROM INTERVAL 0, SUMMARY OF MEANS  
MALES

GROUP (PPM):	0			3			30			300		
	WEEK	0 TO 11	0 TO 12	0 TO 13	0 TO 14	0 TO 15	0 TO 11	0 TO 12	0 TO 13	0 TO 14	0 TO 15	0 TO 11
MEAN		264.5	272.4	277.7	307.5	312.6	276.6	285.2	290.5	307.5	312.6	273.4
S.D.		35.93	36.54	37.04	49.25	49.47	25.94	25.71	26.42	49.47	49.47	53.31
N		30	30	30	10	10	20	20	20	10	10	20
MEAN		264.5	272.4	277.7	307.5	312.6	276.6	285.2	290.5	307.5	312.6	273.4
S.D.		35.93	36.54	37.04	49.25	49.47	25.94	25.71	26.42	49.47	49.47	53.31
N		30	30	30	10	10	20	20	20	10	10	20
MEAN		264.5	272.4	277.7	307.5	312.6	276.6	285.2	290.5	307.5	312.6	273.4
S.D.		35.93	36.54	37.04	49.25	49.47	25.94	25.71	26.42	49.47	49.47	53.31
N		30	30	30	10	10	20	20	20	10	10	20
MEAN		264.5	272.4	277.7	307.5	312.6	276.6	285.2	290.5	307.5	312.6	273.4
S.D.		35.93	36.54	37.04	49.25	49.47	25.94	25.71	26.42	49.47	49.47	53.31
N		30	30	30	10	10	20	20	20	10	10	20
MEAN		264.5	272.4	277.7	307.5	312.6	276.6	285.2	290.5	307.5	312.6	273.4
S.D.		35.93	36.54	37.04	49.25	49.47	25.94	25.71	26.42	49.47	49.47	53.31
N		30	30	30	10	10	20	20	20	10	10	20
MEAN		264.5	272.4	277.7	307.5	312.6	276.6	285.2	290.5	307.5	312.6	273.4
S.D.		35.93	36.54	37.04	49.25	49.47	25.94	25.71	26.42	49.47	49.47	53.31
N		30	30	30	10	10	20	20	20	10	10	20

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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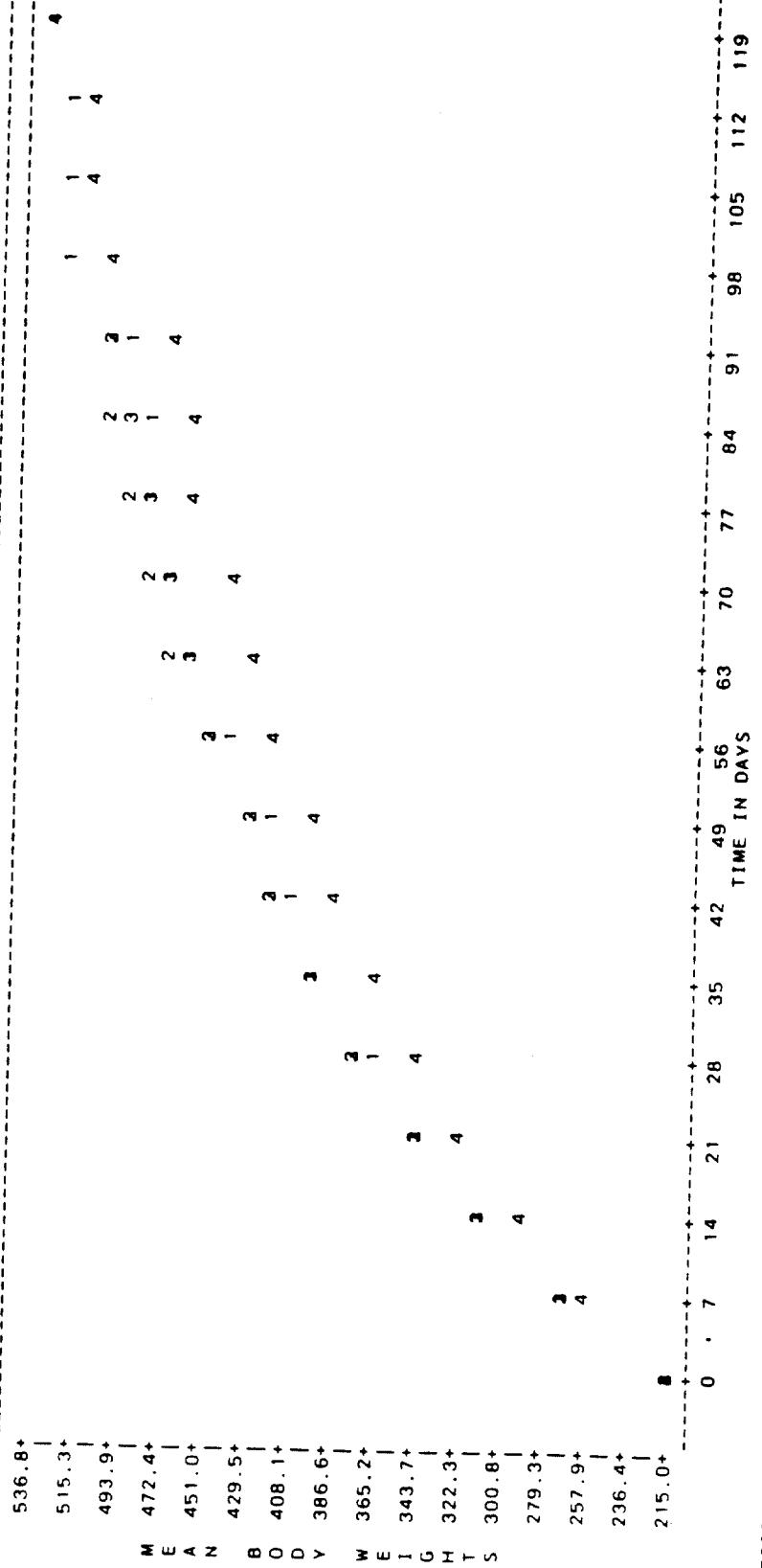
Table 4 (Continued)  
 UC 70480 NINETY DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT GAINS (G) FROM INTERVAL 0, SUMMARY OF MEANS  
 MALES

GROUP (PPM):		0			3			30			300		
WEEK	0 TO 16	MEAN	309.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		S.D.	48.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		N	10	0	0	0	0	0	0	0	0	0	0
0 TO 17	MEAN	322.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	S.D.	47.52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	N	10	0	0	0	0	0	0	0	0	0	0	0

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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FIGURE 1  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
MEAN BODY WEIGHTS (GRAMS) VERSUS TIME  
MALES



FOOTNOTE FOR SYMBOLS:  
1- 0 PPM 2- 3 PPM 3- 30 PPM 4- 300 PPM

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TABLE 5  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT (G). SUMMARY OF MEANS  
FEMALES

GROUP (PPM):				0	3	30	300
WEEK 0	MEAN	164.5	163.3	163.4	164.2		
	S.D.	5.47	7.52	7.10	6.87		
	N	30	20	20	30		
1	MEAN	164.2	184.7	185.0	179.9		
	S.D.	8.15	10.57	11.35	10.01		
	N	30	20	20	30		
2	MEAN	202.2	204.6	203.8	196.2		
	S.D.	10.51	13.16	13.80	12.09		
	N	30	20	20	30		
3	MEAN	217.0	219.2	217.5	208.7		
	S.D.	13.60	15.35	17.91	13.28		
	N	30	20	20	30		

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Table 5 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT (G), SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):	WEEK 4			WEEK 5			WEEK 6			WEEK 7			WEEK 8		
	0	3	30	0	3	30	0	3	30	0	3	30	0	3	30
MEAN	227.4	228.4	230.7	239.0	248.0	249.1	247.4	249.8	256.9	257.1	256.9	249.1	241.1	241.1	249.1
S.D.	14.52	19.23	16.56	15.93	22.76	19.87	22.11	18.19	19.63	18.11	18.19	17.53	16.77	16.77	17.53
N	30	20	20	20	20	20	20	19	20	20	19	19	28	28	28
MEAN	236.4	239.6	239.0	249.1	247.4	249.8	247.4	249.8	256.9	257.1	256.9	249.1	241.1	241.1	249.1
S.D.	16.31	22.11	15.93	19.87	24.50	18.19	24.50	18.19	19.63	18.11	18.19	17.53	16.77	16.77	17.53
N	30	20	20	20	20	20	20	19	20	20	19	19	28	28	28
MEAN	245.9	248.0	249.1	249.8	247.4	249.8	247.4	249.8	256.9	257.1	256.9	249.1	241.1	241.1	249.1
S.D.	19.85	22.76	19.87	19.87	24.50	18.19	24.50	18.19	19.63	18.11	18.19	17.53	16.77	16.77	17.53
N	30	20	20	20	20	20	20	19	20	20	19	19	28	28	28
MEAN	247.0	247.4	249.1	249.8	247.4	249.8	247.4	249.8	256.9	257.1	256.9	249.1	241.1	241.1	249.1
S.D.	17.37	24.50	18.19	18.19	24.50	18.19	24.50	18.19	19.63	18.11	18.19	17.53	16.77	16.77	17.53
N	29	20	20	19	20	19	20	19	20	20	19	19	28	28	28

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Table 5 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT (G). SUMMARY OF MEANS  
FEMALES

GROUP (PPM):	0			3			30			300		
	WEEK	MEAN	S.D.	N	WEEK	MEAN	S.D.	N	WEEK	MEAN	S.D.	N
9	MEAN	262.3	31.38	20	265.2	31.38	19	19	265.5	19.92	19	256.4
9	S.D.	19.54										17.54
9	N	29										28
10	MEAN	268.0	271.6	20	271.6	30.10	22.92	19	271.1	22.92	19	259.9
10	S.D.	19.21										18.51
10	N	29										28
11	MEAN	272.1	274.1	20	274.1	31.53	23.21	19	278.8	23.21	19	266.7
11	S.D.	20.04										18.60
11	N	29										28
12	MEAN	276.3	279.6	20	279.6	30.92	25.00	19	286.2	25.00	19	272.3
12	S.D.	20.99										20.61
12	N	29										28
13	MEAN	278.6	279.1	20	279.1	31.70	25.05	19	285.7	31.70	19	273.1
13	S.D.	20.85										20.80
13	N	29										28

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Table 5 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT (G). SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):	WEEK 14			WEEK 15			WEEK 16			WEEK 17		
	0	3	30	0	0	0	0	0	0	0	0	0
WEEK 14	MEAN S.D. N	287.2 22.04 10	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	288.8 14.21 10	14.21 10	14.95 10	293.0 15.52 10	297.9 15.52 10	300.7 18.88 10
15	MEAN S.D. N	291.8 22.40 10	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	293.0 14.95 10	14.95 10	14.95 10	293.0 14.95 10	297.9 15.52 10	300.7 18.88 10
16	MEAN S.D. N	294.4 23.05 10	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	297.9 15.52 10	15.52 10	15.52 10	297.9 15.52 10	297.9 15.52 10	300.7 18.88 10
17	MEAN S.D. N	298.5 25.41 10	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	0.0 0.00 0	300.7 18.88 10	18.88 10	18.88 10	300.7 18.88 10	300.7 18.88 10	300.7 18.88 10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 6  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT GAINS (G) FROM INTERVAL ZERO. SUMMARY OF MEANS  
FEMALES

GROUP (PPM):	0			3			30			300							
	WEEK	0 TO 1	MEAN	19.7	21.4	21.6	15.7**	S.D.	4.56	5.27	5.76	4.87	N	30	20	20	30
0 TO 2	MEAN	37.7	41.3	40.4	31.9**			S.D.	7.63	7.54	7.81	6.71	N	30	20	20	30
0 TO 3	MEAN	52.5	55.9	54.1	44.5**			S.D.	10.08	9.73	12.49	7.90	N	30	20	20	30
0 TO 4	MEAN	62.9	65.1	67.3	56.8*			S.D.	10.79	14.31	10.89	8.56	N	30	20	20	30
0 TO 5	MEAN	71.9	76.3	75.6	65.5			S.D.	12.36	17.53	10.31	10.32	N	30	20	20	30

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 6 (continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT GAINS (G) FROM INTERVAL ZERO. SUMMARY OF MEANS  
FEMALES

GROUP (PPM):	0			3			30			300		
	WEEK	0 TO 6										
0 TO 6	MEAN	81.3		84.7			85.8			73.1*		
	S.D.	15.86		18.85			14.53			10.75		
	N	30		20			20			30		
0 TO 7	MEAN	82.4		84.1			86.2			76.4		
	S.D.	13.42		19.92			13.45			11.58		
	N	29		20			19			28		
0 TO 8	MEAN	90.4		93.9			93.3			84.3		
	S.D.	13.88		25.79			15.15			12.70		
	N	29		20			19			28		
0 TO 9	MEAN	97.8		102.0			101.9			91.6		
	S.D.	15.69		26.86			14.85			12.73		
	N	29		20			19			28		
0 TO 10	MEAN	103.4		108.3			107.5			95.1		
	S.D.	15.25		25.51			18.02			13.40		
	N	29		20			19			28		

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

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TABLE 6 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 BODY WEIGHT GAINS (G) FROM INTERVAL ZERO. SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):		0			3			30			300		
WEEK	0 TO 11	MEAN	107.5		110.8			115.1			102.0		
		S.D.	15.97		26.72			18.65			13.55		
		N	20		29			19			28		
0 TO 12	MEAN	111.7			116.3			122.6			107.5		
	S.D.	17.16			26.37			20.47			15.89		
	N	20			29			19			28		
0 TO 13	MEAN	114.1			115.8			122.1			108.4		
	S.D.	17.00			26.87			20.61			16.05		
	N	20			29			19			28		
0 TO 14	MEAN	120.9			0.0			0.0			122.8		
	S.D.	18.33			0.00			0.00			9.05		
	N	10			0			0			10		
0 TO 15	MEAN	125.5			0.0			0.0			126.9		
	S.D.	18.81			0.00			0.00			11.89		
	N	10			0			0			10		

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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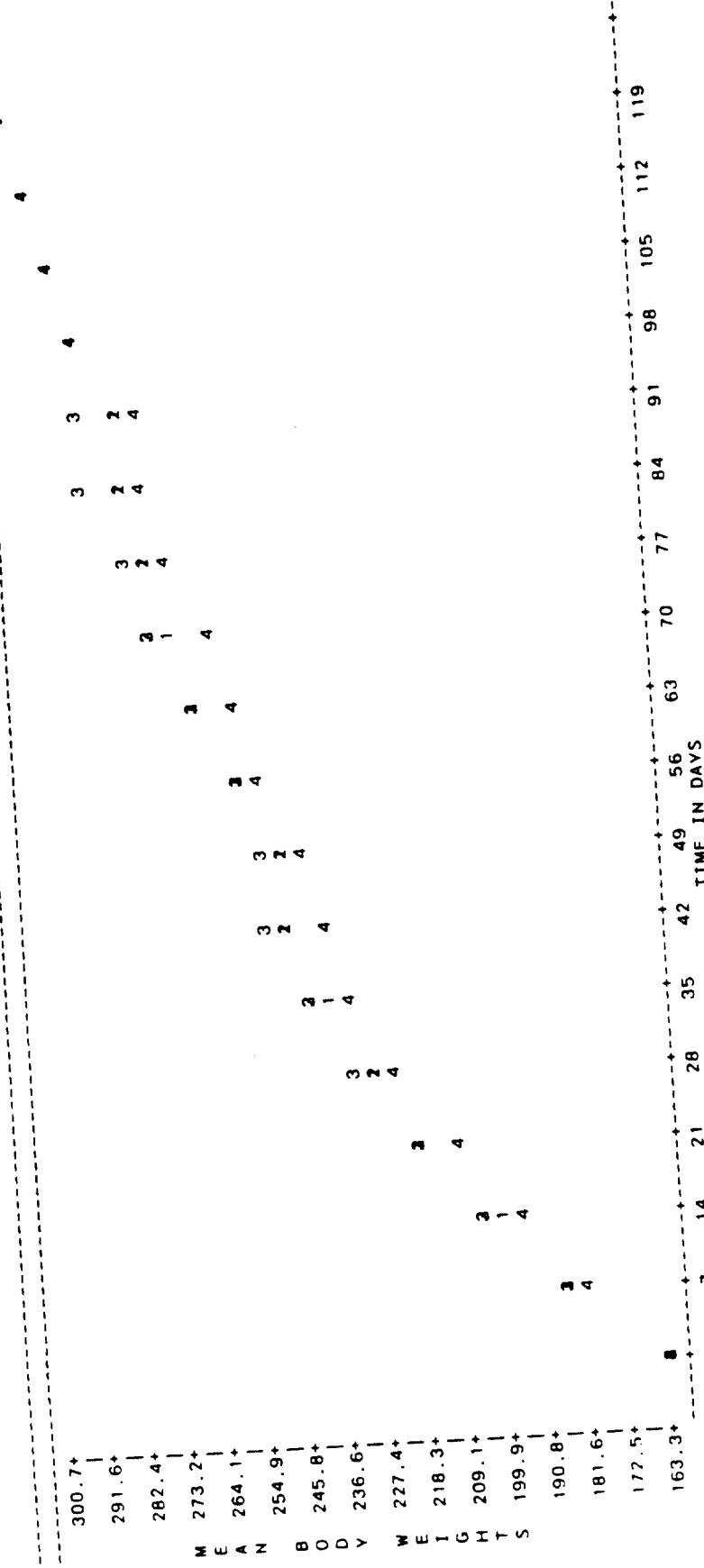
TABLE 6 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
BODY WEIGHT GAINS (G) FROM INTERVAL ZERO. SUMMARY OF MEANS  
FEMALES

		GROUP (PPM):			300		
		0	3	30	300		
WEEK	0 TO 16	MEAN	0.0	0.0	131.8	12.13	10
		S.D.	0.00	0.00			
		N	10	0			
0 TO 17		MEAN	128.1	19.55	0.0	0.0	
		S.D.					
		N	10	0			
0 TO 17		MEAN	132.2	22.01	0.0	0.0	
		S.D.					
		N	10	0			

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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FIGURE 2  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
MEAN BODY WEIGHTS (GRAMS) VERSUS TIME  
FEMALES



FOOTNOTE FOR SYMBOLS:  
 1- 0 PPM    2- 3 PPM    3- 30 PPM    4- 300 PPM

TABLE 7  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
MALES

GROUP (PPM):	0	300		
		3	30	300
DAY	2	MEAN	S.D.	N
4	22.0	23.2*	22.1	18.6**
	1.59	1.69	1.40	2.14
	30	20	20	30
7	24.4	24.9	24.0	22.9**
	1.51	1.44	1.71	1.92
	30	20	20	30
9	24.3	24.8	23.9	23.6
	1.81	1.46	2.09	1.93
	30	20	20	30
11	24.0	24.4	24.4	23.7
	2.25	1.49	2.32	1.97
	30	20	20	30

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 7 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 MALES

GROUP (PPM):	0	3			30			300		
		DAY	14	MEAN	S.D.	N	25.2	25.59	25.2	24.4
16				24.7	1.91	30	1.54	2.0	2.10	2.10
									2.10	30
18				24.4	2.01	29	1.57	19	2.26	2.26
									2.26	30
21				24.7	1.94	30	1.85	20	2.22	2.22
									2.22	30
23				24.2	1.91	30	1.37	19	2.06	2.06
									2.06	30

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Report 49-

Table 7 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY), SUMMARY OF MEANS  
MALES

GROUP (PPM):	0	300		
		3	30	300
DAY 25	MEAN S.D. N	25.0 1.76 30	25.6 1.61 20	25.2 3.45 19
28	MEAN S.D. N	25.0 1.69 30	26.2** 1.15 20	25.4 2.88 20
30	MEAN S.D. N	23.9 2.14 30	25.5* 1.43 20	25.5* 2.65 20
32	MEAN S.D. N	24.5 1.83 30	25.9 1.82 20	26.0 2.82 20
35	MEAN S.D. N	25.3 1.84 30	25.6 1.90 20	25.2 2.81 20

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 7 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 MALES

GROUP (PPM):		0			3			30			300		
DAY	37	MEAN	25.4		25.6			26.0			24.3		
		S.D.	2.18		2.26			3.46			2.51		
		N	29		20			19			30		
39		MEAN	25.4		25.5			25.6			23.6**		
		S.D.	1.81		1.87			2.96			2.21		
		N	30		20			20			30		
42		MEAN	24.5		25.0			26.0			24.2		
		S.D.	2.08		1.43			2.94			2.30		
		N	29		20			20			30		
44		MEAN	24.9		25.2			26.9**			24.3		
		S.D.	2.31		2.53			3.26			2.16		
		N	30		20			20			30		
46		MEAN	25.1		26.7*			27.3**			25.4		
		S.D.	2.26		2.62			2.76			2.18		
		N	30		20			20			30		

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
MALES

GROUP (PPM) :	DAY	49	0			3			300		
			MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
51			25.4	2.13	30	26.1	1.89	20	26.6	2.81	20
53			24.1	2.58	30	25.2	1.88	20	25.4	3.21	20
56			25.4	2.24	30	26.9	1.76	20	25.8	3.05	20
58			25.7	2.14	30	27.0	1.70	18	25.5	2.92	20
			MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Table 7 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
MALES

GROUP (PPM):	DAY	0			3			30			300		
		MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
60	60	25.0	2.13	30	26.0	2.14	20	25.0	3.12	20	24.2	2.64	30
63	63	25.3	2.09	30	26.4	1.91	20	25.5	3.09	20	24.6	2.43	30
65	65	23.9	2.21	30	25.1	2.08	20	24.7	3.22	20	23.8	2.10	30
67	67	24.1	2.30	30	25.2	1.77	20	25.3	3.74	20	23.6	2.23	30
70	70	24.5	2.03	30	26.4**	1.77	20	25.4	3.45	20	25.3	2.18	30

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Table 7 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 MALES

GROUP (PPM):	0	300		
		3	30	300
DAY 72				
	MEAN	23.6	25.4	24.5
	S.D.	1.95	1.99	3.06
	N	30	20	20
74	MEAN	24.0	25.7	24.1
	S.D.	2.08	1.88	2.57
	N	30	20	30
77	MEAN	24.4	25.8	24.2
	S.D.	2.28	1.77	3.40
	N	30	20	30
79	MEAN	23.8	25.3	24.9
	S.D.	2.10	2.22	2.67
	N	30	20	20
81	MEAN	24.9	26.2	24.7
	S.D.	1.97	2.37	3.01
	N	30	20	20

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Table 7 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 MALES

GROUP (PPM):				0	3	30	300
DAY	84	MEAN	S.D.				
		N	N				
86	MEAN	24.3	2.70*	25.2	24.4	23.7	
	S.D.	3.81	2.00	2.34	3.07	2.27	
	N	30	20	19	19	30	
88	MEAN	23.8	2.19	27.0*	25.0	23.8	
	S.D.	1.91	2.00	4.02	3.83	3.43	
	N	30	20	20	20	30	
91	MEAN	23.4	2.22	24.4	24.2	23.6	
	S.D.	2.22	2.00	2.21	2.84	2.59	
	N	30	20	20	20	30	
93	MEAN	22.1	2.65	23.8	23.6	22.8	
	S.D.	2.65	1.0	2.08	2.70	2.22	
	N	10	10	20	20	30	

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

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Report 49-11

Table 7 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
MALES

GROUP (PPM):	DAY	0			3			30			300		
		MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
95	95	22.9	0.0	10	1.99	0.00	10	0.0	0.00	0	25.8*	2.80	10
98	98	24.3	0.0	10	2.27	0.00	10	0.0	0.00	0	26.1	3.00	10
100	100	24.1	0.0	10	2.36	0.00	10	0.0	0.00	0	26.9*	3.29	10
102	102	22.5	0.0	10	1.63	0.00	10	0.0	0.00	0	25.0	3.40	10
105	105	24.5	0.0	10	1.72	0.00	10	0.0	0.00	0	26.4	2.83	10

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

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Table 7 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 MALES

GROUP (PPM):	0			3			30			300		
	DAY	MEAN	S.D.	N	DAY	MEAN	S.D.	N	DAY	MEAN	S.D.	N
107		24.1	1.98	10		0.0	0.00	0		0.0	0.00	0
109		23.7	1.81	10		0.0	0.00	0		0.0	0.00	0
112		24.1	1.68	10		0.0	0.00	0		0.0	0.00	0
114		30.1	2.87	10		0.0	0.00	0		0.0	0.00	0
116		23.7	1.72	10		0.0	0.00	0		0.0	0.00	0

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

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Table 7 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY), SUMMARY OF MEANS  
 MALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
DAY 119	26.0	5.38	10	0.0	0.00	0	0.0	0.00	0	25.2	2.94	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 8  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY), SUMMARY OF MEANS  
FEMALES

GROUP (PPM):		0		3		30		300	
DAY	1	MEAN	15.7	15.8	15.7	15.6	15.7	12.7**	
		S.D.	1.92	2.13	2.0	2.0	1.68	1.72	
		N	30				30	30	
3		MEAN	17.4	17.5	17.0	1.43	1.49	16.4**	
		S.D.	1.28	1.58	2.0	2.0	1.49	1.49	
		N	30				30	30	
6		MEAN	18.3	18.3	18.5	1.56	1.56	18.1	
		S.D.	1.26	1.73	2.0	2.0	1.47	1.47	
		N	30				30	30	
8		MEAN	17.9	17.4	17.4	1.74	1.74	17.2	
		S.D.	1.56	1.38	2.0	2.0	1.44	1.44	
		N	30				30	30	
10		MEAN	18.6	19.1	18.5	1.91	1.91	17.1**	
		S.D.	1.58	2.19	2.0	2.0	1.55	1.55	
		N	30				30	30	

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 8 (Continued)  
 UC 704BD NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):	DAY	13	0			3			30			300		
			MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
15			18.6	1.57	30	18.8	1.59	20	18.6	1.65	19	17.7*	1.43	30
17			18.2	1.80	29	18.0	2.41	19	17.5	1.91	20	16.9**	1.39	30
20			17.6	1.78	30	17.9	1.80	19	18.1	2.27	20	17.2	1.68	30
22			18.2	1.77	30	18.3	1.46	20	18.3	1.64	20	17.3*	1.18	29

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
 \*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 8 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):	0			3			30			300		
	DAY	MEAN	S.D.	N	DAY	MEAN	S.D.	N	DAY	MEAN	S.D.	N
24	MEAN	17.8	2.27	28	17.3	3.94	20	18.9	1.82	20	17.7	1.44
	S.D.											
	N											
27	MEAN	18.5	1.96	30	18.6	2.68	19	19.3	1.54	20	17.4*	1.14
	S.D.											
	N											
29	MEAN	17.9	1.98	28	18.0	2.30	20	19.5**	1.89	19	18.0	1.53
	S.D.											
	N											
31	MEAN	19.1	2.32	30	18.2	3.25	20	19.6	1.69	20	18.1	1.61
	S.D.											
	N											
34	MEAN	18.8	1.80	30	19.4	2.31	20	19.6	1.66	20	18.1	1.56
	S.D.											
	N											

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Report 49

TABLE 8 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY), SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):	DAY	0			3			30			300		
		MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
	36	18.3	2.84	30	17.4	2.38	20	16.8*	1.40	19	15.9**	2.05	30
	38	18.9	2.51	29	19.0	2.69	20	19.2	2.42	19	18.1	1.86	30
	41	18.4	2.10	29	17.8	2.29	20	18.8	2.53	19	17.3	1.31	29
	43	17.3	2.64	29	18.2	2.86	20	18.6	3.21	20	18.1	5.16	28
	45	19.4	2.47	29	18.8	3.44	20	20.6	3.92	19	19.9	4.02	28

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
 \*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Report 49-11

TABLE 8 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
FEMALES

GROUP (PPM):	0	3			30			300																		
		DAY	48	MEAN	S.D.	N	DAY	50	MEAN	S.D.	N	DAY	52	MEAN	S.D.	N	DAY	55	MEAN	S.D.	N	DAY	57	MEAN	S.D.	N
				18.7	1.92	29			18.9	1.86	20			18.4	1.70	19			18.4	1.51	28			18.4	1.51	28
									17.2	2.39	19			19.3	5.05	18			17.0	1.71	28			17.0	1.71	28
									19.1	2.86	18			19.3	2.23	19			18.4	1.95	28			18.4	1.95	28
									18.8	2.86	18			18.8	1.97	19			18.3	1.79	28			18.3	1.79	28
									18.3	3.26	18			18.9	1.78	19			18.1	1.65	28			18.1	1.65	28

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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Report 49

UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
FEMALES

GROUP (PPM)	DAY	0			3			30			300		
		MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
	59	18.2	1.89	29	18.6	3.32	20	18.5	2.49	19	17.7	1.56	28
	62	19.0	1.82	29	19.6	2.60	20	19.7	2.28	19	18.7	1.79	28
	64	18.4	2.26	29	18.4	2.46	20	18.5	1.52	19	18.5	1.43	28
	66	18.4	2.13	27	18.8	2.53	20	18.3	2.63	19	16.5**	2.98	28
	69	18.7	1.97	27	18.2	1.73	18	19.1	1.44	19	18.3	1.54	28

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 8 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
FEMALES

GROUP (PPM):				0		3		30		300	
DAY	71	MEAN	17.0	17.5	18.3	18.3	18.0	17.0	17.0	17.0	17.0
		S.D.	1.90	2.85	2.35	2.35	2.35	2.35	2.35	2.35	2.35
		N	29	20	19	19	19	19	19	19	19
73		MEAN	17.5	16.9	19.2*	19.2*	19.3	18.3	18.3	18.3	18.3
		S.D.	2.43	2.03	1.97	1.97	1.97	1.80	1.80	1.80	1.80
		N	29	20	19	19	19	28	28	28	28
76		MEAN	18.8	18.6	19.4	19.4	19.4	17.9	17.9	17.9	17.9
		S.D.	1.99	2.37	1.80	1.80	1.80	1.60	1.60	1.60	1.60
		N	29	20	19	19	19	28	28	28	28
78		MEAN	16.8	16.6	18.5**	18.5**	17.8	17.8	17.8	17.8	17.8
		S.D.	2.31	2.05	2.63	2.63	2.63	1.70	1.70	1.70	1.70
		N	29	20	19	19	19	28	28	28	28
80		MEAN	17.7	17.3	18.8	18.8	17.9	17.9	17.9	17.9	17.9
		S.D.	2.23	2.59	2.00	2.00	2.00	1.89	1.89	1.89	1.89
		N	29	20	19	19	19	28	28	28	28

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 8 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
FEMALES

GROUP (PPM):	DAY	0			3			30			300		
		MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
83	0	18.4	2.01	29	18.1	2.38	20	18.5	2.64	19	18.5	1.66	28
85	0	17.2	2.05	29	16.1	2.22	20	18.6*	2.21	19	17.2	1.93	28
87	0	18.5	2.70	29	19.1	3.29	20	20.1	2.86	19	18.6	2.65	28
90	0	17.8	1.63	29	15.9**	2.09	20	18.0	2.43	19	17.3	1.71	28
92	0	17.4	1.98	10	0.0	0.00	0	0.0	0.00	0	20.0*	2.24	10

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL  
\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 8 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY), SUMMARY OF MEANS  
 FEMALES

GROUP (PPM):				0	3	30	300
DAY	94	MEAN	S.D.	18.1	0.0	0.0	18.8
		S.D.	N	1.16	0.00	0.00	2.11
	97	MEAN	S.D.	19.5	0.0	0.0	19.5
		S.D.	N	1.82	0.00	0.00	2.14
				10	0	0	10
	99	MEAN	S.D.	18.7	0.0	0.0	19.4
		S.D.	N	1.84	0.00	0.00	2.06
				10	0	0	10
	101	MEAN	S.D.	18.3	0.0	0.0	18.3
		S.D.	N	1.72	0.00	0.00	2.60
				10	0	0	10
	104	MEAN	S.D.	18.7	0.0	0.0	18.5
		S.D.	N	1.94	0.00	0.00	2.14
				10	0	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 8 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FOOD CONSUMPTION (GRAMS/ANIMAL/DAY). SUMMARY OF MEANS  
FEMALES

GROUP (PPM):	DAY	106	0			3			30			300		
			MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
108			19.8	1.72	10	0.0	0.00	0	0.0	0.00	0	19.2	2.36	10
111			17.8	2.34	10	0.0	0.00	0	0.0	0.00	0	16.8	1.98	10
113			18.5	1.02	10	0.0	0.00	0	0.0	0.00	0	18.1	1.94	10
115			20.6	2.81	10	0.0	0.00	0	0.0	0.00	0	19.6	3.10	10
NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP														

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TABLE 8 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 FOOD CONSUMPTION (GRAMS/ANIMAL/DAY), SUMMARY OF MEANS  
 FEMALES

GROUP (PPM) :	300		
	0	3	30
DAY 118	MEAN	21.0	0.0
	S.D.	3.79	0.00
	N	10	0

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 9  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
CALCULATED DOSAGE OF COMPOUND INGESTED (MG/KG BODYWEIGHT/DAY)  
MALES

GROUP (PPM):		3		30		300	
DAY	0 TO 7	MEAN	0.3	2.9		27.6	
		S.D.	0.01	0.13		1.81	
		N	20	20		30	
DAY	7 TO 14	MEAN	0.3	2.6		26.4	
		S.D.	0.01	0.14		1.56	
		N	20	20		30	
DAY	14 TO 21	MEAN	0.2	2.3		23.5	
		S.D.	0.01	0.08		1.28	
		N	20	20		30	
DAY	21 TO 28	MEAN	0.2	2.1		21.3	
		S.D.	0.01	0.17		1.76	
		N	20	20		30	
DAY	28 TO 35	MEAN	0.2	2.0		20.2	
		S.D.	0.01	0.10		1.24	
		N	20	20		30	
DAY	35 TO 42	MEAN	0.2	1.9		19.1	
		S.D.	0.01	0.09		1.09	
		N	20	20		30	
DAY	42 TO 49	MEAN	0.2	1.9		19.2	
		S.D.	0.01	0.09		1.09	
		N	20	20		30	

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Table 9 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 CALCULATED DOSAGE OF COMPOUND INGESTED (MG/KG BODYWEIGHT/DAY)  
 MALES

GROUP (PPM):		3	30	300
DAY	49 TO 56	0.2 0.01	1.8 0.10	17.9 1.47
	MEAN S.D. N	20	20	30
DAY	56 TO 63	0.2 0.01	1.7 0.11	17.3 1.04
	MEAN S.D. N	20	20	30
DAY	63 TO 70	0.2 0.01	1.6 0.12	16.9 0.74
	MEAN S.D. N	20	20	30
DAY	70 TO 77	0.2 0.01	1.6 0.09	16.2 1.37
	MEAN S.D. N	20	20	30
DAY	77 TO 84	0.2 0.01	1.5 0.08	15.7 0.93
	MEAN S.D. N	20	20	30
DAY	84 TO 91	0.1 0.01	1.5 0.12	15.1 1.11
	MEAN S.D. N	20	20	30

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TABLE 10  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
CALCULATED DOSAGE OF COMPOUND INGESTED (MG/KG BODYWEIGHT/DAY)  
FEMALES

GROUP (PPM):		0 TO 6		3		30		300	
DAY	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
DAY 6 TO 13	0.3	0.02	20	0.3	0.02	20	0.18	0.02	20
DAY 13 TO 20	0.3	0.02	20	0.15	0.02	20	27.4	1.66	30
DAY 20 TO 27	0.3	0.02	20	0.15	0.02	20	27.6	1.40	30
DAY 27 TO 34	0.2	0.03	20	0.15	0.02	20	25.4	1.30	30
DAY 34 TO 41	0.2	0.02	20	0.11	0.02	20	24.2	1.08	30
DAY 41 TO 48	0.2	0.01	20	0.16	0.02	20	24.1	1.15	30
				0.20		19	22.0	1.03	30
				0.20		19	23.6	3.13	28
				0.20		19	23.6	3.13	28

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TABLE 10 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 CALCULATED DOSAGE OF COMPOUND INGESTED (MG/KG BODYWEIGHT/DAY)  
 FEMALES

GROUP (PPM):		3		30		300	
DAY	48 TO 55	MEAN	0.2	2.3	21.9		
		S.D.	0.01	0.31	1.61		
		N	19	19	28		
DAY	55 TO 62	MEAN	0.2	2.2	21.6		
		S.D.	0.02	0.18	1.35		
		N	20	19	28		
DAY	62 TO 69	MEAN	0.2	2.1	20.7		
		S.D.	0.02	0.14	2.00		
		N	20	19	28		
DAY	69 TO 76	MEAN	0.2	2.1	20.7		
		S.D.	0.02	0.18	2.00		
		N	20	19	28		
DAY	76 TO 83	MEAN	0.2	2.0	20.2		
		S.D.	0.02	0.18	1.30		
		N	20	19	28		
DAY	83 TO 90	MEAN	0.2	2.0	20.1		
		S.D.	0.02	0.18	1.20		
		N	20	19	28		

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TABLE 11  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
CLINICAL OBSERVATION. SUMMARY OF INCIDENCE  
MALES

TABLE RANGE: GROUP:	DAY 0 TO DAY 119			
	1	2	3	4
BODY/INTEGUMENT				
-ALOPECIA	1	0	0	0
-TRAUMA, LEGS	0	0	0	1
-TRAUMA, HEAD	0	0	1	1
EYES/EARNS/NOSE				
-NASAL DISCHARGE	0	0	2	2
-OCULAR DISCHARGE	1	1	1	2
ORAL/DENTAL				
-MALOCCLUSION	0	0	0	2

1- 0 PPM    2- 3 PPM    3- 30 PPM    4- 300 PPM

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TABLE 12  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
CLINICAL OBSERVATIONS, SUMMARY OF INCIDENCE  
FEMALES

TABLE RANGE: GROUP:	DAY			
	1	2	3	4
BODY/INTEGUMENT	1	1	0	1
-ALOPECIA	0	1	0	0
-DERMATITIS	1	0	0	0
-TRAUMA, LEGS	0	1	0	0
-TRAUMA, HEAD	0	0	0	0
EYES/EARS/NOSE	1	0	2	0
-NASAL DISCHARGE	1	0	0	0
-OCULAR DISCHARGE	0	2	0	0
ORAL/DENTAL	0	2	0	0
-MALOCCLUSION	1- 0 PPM	2- 3 PPM	3- 30 PPM	4- 300 PPM

Table 13

**Mean Results of Hematologic Determinations for CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats**

Dosage	7-Week Results												
	WBC	RBC		Hgb		Mhgb		Hct		MCV	MCH	MCHC	Plt
		Males	Females	Males	Females	Males	Females	Males	Females				
300 PP <sup>a</sup>	14.4 (2.5)	8.0 (0.3)	15.5 (0.4)	0.22 (0.14)	42.6 <sup>a</sup> (1.1)	53.1 (1.5)	19.3 (0.7)	36.3 (0.4)	1300 <sup>b</sup> (73)				
30 PP <sup>a</sup>	14.8 (4.5)	8.3 (0.3)	15.8 (0.4)	0.22 (0.14)	44.1 (1.4)	53.2 (1.3)	19.1 (0.6)	35.9 (0.5)	1274 <sup>a</sup> (113)				
3 PP <sup>a</sup>	14.7 (3.0)	8.0 (0.3)	15.5 (0.3)	0.30 (0.14)	42.7 <sup>a</sup> (1.1)	53.4 (0.9)	19.3 (0.4)	36.2 (0.4)	1199 (124)				
0 PP <sup>a</sup>	13.9 (2.5)	8.3 (0.5)	15.8 (0.6)	0.22 (0.14)	44.1 (1.7)	53.4 (1.4)	19.1 (0.7)	35.8 (0.6)	1170 (87)				
<b>FEMALES</b>													
300 PP <sup>a</sup>	13.5 <sup>a</sup> (5.3)	7.8 (0.3)	15.3 (0.4)	0.33 (0.35)	41.8 (1.5)	53.9 (0.9)	19.7 (0.6)	36.5 (0.7)	1378 <sup>a</sup> (132)				
30 PP <sup>a</sup>	9.2 (1.5)	7.7 (0.3)	15.5 (0.4)	0.09 (0.08)	42.3 (1.3)	54.9 (1.4)	20.1 (0.6)	36.6 (0.4)	1213 (137)				
3 PP <sup>a</sup>	8.7 (2.0)	7.9 (0.2)	15.7 <sup>b</sup> (0.3)	0.19 <sup>a</sup> (0.12)	43.2 (0.8)	54.6 (0.6)	19.9 (0.5)	36.4 (0.6)	1162 (87)				
0 PP <sup>a</sup>	8.1 (3.4)	7.7 (0.3)	15.2 (0.5)	0.08 (0.08)	42.1 (1.5)	54.3 (1.9)	19.7 (0.8)	36.3 (0.7)	1258 (108)				

<sup>a</sup>) = Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

WBC = White blood cells ( $\times 10^3/\text{mm}^3$ )

RBC = Red blood cells ( $\times 10^6/\text{mm}^3$ )

Hgb = Hemoglobin (g/100 ml)

Mhgb = Mean hemoglobin (pg)

Hct = Hematocrit (%)

MCV = Mean corpuscular volume ( $\mu\text{l}$ )

MCH = Mean corpuscular hemoglobin (pg)

MCHC = Mean corpuscular hemoglobin concentration (%/100 ml)

Table 14

**Mean Results of Hematologic Determinations for CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats**

Dosage	13-Week Results									
	WBC	RBC		Hgb		Mhgb		Hct		MALES
		Males	Females	Males	Females	Males	Females	Males	Females	
300 ppm	12.0 (1.5)	8.1 <sup>b</sup> (0.4)	14.7 <sup>b</sup> (0.3)	0.19 (0.16)	40.7 <sup>c</sup> (1.0)	50.2 (2.0)	18.1 (0.8)	36.0 (0.4)	1239 <sup>b</sup> (108)	
30 ppm	12.0 (2.6)	8.5 (0.6)	15.4 (0.6)	0.19 (0.18)	42.3 (1.9)	50.0 (2.4)	18.2 (0.8)	36.2 <sup>b</sup> (0.4)	1195 (121)	
3 ppm	11.5 (2.2)	8.7 (0.4)	15.4 (0.6)	0.19 (0.05)	42.9 (1.8)	49.5 (1.0)	17.8 (0.4)	36.0 <sup>a</sup> (0.3)	1133 (89)	
0 ppm	11.0 (2.8)	8.8 (0.4)	15.5 (0.6)	0.13 (0.22)	43.6 (1.8)	49.4 (1.9)	17.7 (0.7)	35.7 (0.5)	1090 (143)	
FEMALES										
300 ppm	7.4 (1.9)	7.4 (0.3)	14.4 (0.7)	0.18 (0.20)	39.3 <sup>a</sup> (2.2)	53.1 (1.2)	19.5 (0.3)	36.8 <sup>b</sup> (0.6)	1241 (127)	
30 ppm	6.2 (1.5)	7.6 (0.4)	15.2 (0.4)	0.10 (0.10)	41.2 (1.4)	54.2 (1.5)	20.0 (0.8)	36.8 <sup>b</sup> (0.5)	1053 (145)	
3 ppm	6.9 (1.4)	8.4 <sup>a</sup> (0.3)	16.2 <sup>b</sup> (0.5)	0.18 (0.16)	44.7 <sup>b</sup> (1.5)	53.4 (0.7)	19.4 (0.4)	36.3 (0.6)	1033 (103)	
0 ppm	5.8 (1.6)	7.8 (1.0)	14.9 (1.4)	0.20 (0.18)	41.5 (3.7)	53.7 (3.1)	19.3 (1.1)	36.0 (0.7)	1138 (200)	

( ) = Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 &gt; p &gt; 0.01; b = 0.01 &gt; p &gt; 0.001; c = p &lt; 0.001

WBC = White blood cells ( $\times 10^3/\text{mm}^3$ )RBC = Red blood cells ( $\times 10^6/\text{mm}^3$ )

Hgb = Hemoglobin (g/dl)

Mhgb = Methemoglobin (g/dl)

Hct = Hematocrit (%)

MCV = Mean corpuscular volume ( $\mu\text{l}$ )

MCH = Mean corpuscular hemoglobin (pg)

MCHC = Mean corpuscular hemoglobin concentration (g/dl)

Plt = Platelets ( $\times 10^3/\text{mm}^3$ )

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Table 15

Mean Results of Hematologic Determinations for CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

17-Week Results

Dosage	WBC		RBC		Hgb		Mhgb		Hct		MCV		MCH		MCHC		Plt	
	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females
300 ppm	10.0 (2.0)	8.2 (0.5)	14.6 (0.4)	14.6 (0.22)	0.36 <sup>a</sup> (0.22)	0.36 <sup>a</sup> (0.22)	40.8 (1.6)	40.8 (1.6)	49.7 (1.6)	49.7 (1.6)	17.8 (0.7)	17.8 (0.7)	35.7 (0.5)	35.7 (0.5)	1172 (147)	1172 (147)		
0 ppm	11.0 (1.8)	8.6 (0.6)	15.0 (0.6)	15.0 (0.15)	0.15 (0.15)	0.15 (0.15)	41.8 (2.3)	41.8 (2.3)	48.9 (2.2)	48.9 (2.2)	17.6 (0.9)	17.6 (0.9)	35.9 (0.6)	35.9 (0.6)	1139 (131)	1139 (131)		
FEMALES																		
300 ppm	6.0 (1.8)	7.6 (0.2)	14.8 (0.4)	14.8 (0.19)	0.24 (0.19)	0.24 (0.19)	40.9 (1.2)	40.9 (1.2)	53.9 (1.1)	53.9 (1.1)	19.5 (0.6)	19.5 (0.6)	36.2 (0.4)	36.2 (0.4)	1108 (108)	1108 (108)		
0 ppm	5.4 (1.2)	7.8 (0.3)	14.9 (0.7)	14.9 (0.30)	0.25 (0.30)	0.25 (0.30)	41.4 (2.5)	41.4 (2.5)	52.8 (2.1)	52.8 (2.1)	19.1 (0.6)	19.1 (0.6)	36.1 (0.8)	36.1 (0.8)	1034 (128)	1034 (128)		

( ) = Standard deviation

Superscript denotes level of significance vs. control:  
 $\alpha = 0.05 > p > 0.01$

WBC = White blood cells ( $\times 10^3/\text{mm}^3$ )      MCV = Mean corpuscular volume ( $\mu\text{m}^3$ )  
 RBC = Red blood cells ( $\times 10^6/\text{mm}^3$ )      MCH = Mean corpuscular hemoglobin (pg)  
 Hgb = Hemoglobin (g/dl)      MCHC = Mean corpuscular hemoglobin concentration (g/dl)  
 Mhgb = Methemoglobin (g/dl)      Plt = Platelets ( $\times 10^3/\text{mm}^3$ )  
 Hct = Hematocrit (%)

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Table 16

Mean and Median Results of Leukocyte Differentials and Heinz Body Counts for CD $\bullet$  Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

7-Week Results									
Dosage	MALES				FEMALES				
	Neutro- phils*†	Lympho- cytes*†	Mono- cytes*†	Baso- phils*†	Eosino- phils*†	Banded	Neutro- phils*†	Large Mono- cytes*†	Immature Granulo- cytes*†
300 ppm	1594 (755)	11882 (2382)	704 [374]	0 [0]	70 [144]	0 [0]	0 [0]	0 [0]	0 [0]
30 ppm	1894 (1103)	11901 (3845)	980 [589]	0 [0]	54 [110]	0 [0]	0 [0]	0 [0]	0 [0]
3 ppm	2006 (1108)	11940 (3200)	548 [396]	0 [0]	130 [85]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm 77 of 671	1415 (635)	11893 (2411)	461 [179]	0 [0]	126 [84]	0 [0]	0 [0]	0 [0]	0 [0]
300 ppm	832 (495)	11735* (4637)	588* [420]	0 [0]	48 [50]	0 [0]	0 [0]	0 [0]	0 [0]
30 ppm	769 (307)	7622 (1187)	563 [197]	0 [0]	177 [76]	0 [0]	0 [0]	0 [0]	0 [0]
3 ppm	713 (381)	7389 (1808)	392 [192]	0 [0]	93 [48]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm	808 (333)	6802 (2841)	302 [128]	0 [0]	118 [43]	0 [0]	0 [0]	0 [0]	0 [0]

\*Mean

( ) Standard deviation  
Superscript denotes level of significance vs. control: a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

† cells/mm<sup>3</sup>  
NRBC = Nucleated red blood cells/100 WBC's  
Heinz bodies = positive cell/100 RBC's

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\*\*Median

[ ] Quartile deviation

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Table 17

**Mean and Median Results of Leukocyte Differentials and Heinz Body Counts for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats**

Dosage	13-Week Results									
	Neutro-		Lympho-		Mono-		Baso-		Eosino-	
	phils†	cytes†	phils†	cytes†	phils†	cytes†	phils†	cytes†	phils†	cytes†
300 ppm	1874 (385)	9117 (1422)	673 [274]	0 [0]	118 [72]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
30 ppm	1872 (978)	9196 (2542)	722 [227]	0 [0]	133 [112]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
3 ppm	1833 (1143)	8857 (2293)	460 [369]	0 [0]	175 [48]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm	1780 (967)	8272 (2606)	767 [312]	0 [0]	246 [82]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
<b>MALES</b>										
300 ppm	898 (326)	5984 (1785)	307 [176]	0 [0]	111 [98]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
30 ppm	978 (593)	4898 (1044)	214 [86]	0 [0]	140 [101]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
3 ppm	675 (316)	5700 (1430)	375 [116]	0 [0]	106 [81]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm	751 (396)	4672 (1360)	277 [110]	0 [0]	108 [52]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
<b>FEMALES</b>										
300 ppm	898 (326)	5984 (1785)	307 [176]	0 [0]	111 [98]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
30 ppm	978 (593)	4898 (1044)	214 [86]	0 [0]	140 [101]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
3 ppm	675 (316)	5700 (1430)	375 [116]	0 [0]	106 [81]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm	751 (396)	4672 (1360)	277 [110]	0 [0]	108 [52]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]

Mean  
() Standard deviation

† Median  
[] Quartile deviation

NRBC = Nucleated red blood cells/100 WBC's  
Heinz bodies = positive cell/100 RBC's

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Table 18

**Mean and Median Results of Leukocyte Differentials and Heinz Body Counts for CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study In Rats**

**17-Week Results**

Dosage	17-Week Results									
	Neutro- phils*†	Lympho- cytes*†	Mono- cytes*‡	Baso- phils*‡	Eosino- phil*‡	Banded Neutro- phils*‡	NRBC*‡	Large Mono- cytes*†	Immature Granulo- cytes*†	Heinz Bodies*‡
300 ppm	1668 (454)	7153 (1833)	957 [105]	0 [0]	112 [92]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm	1890 (872)	7776 (1832)	1031 [261]	0 [0]	261 [126]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
FEMALES										
300 ppm	728 (164)	4845 (1727)	427 [122]	0 [0]	0 [31]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]
0 ppm	1042 (970)	3912 (929)	370 (186)	0 [0]	72 [63]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]

\*Mean

( ) Standard deviation

† cells/mm<sup>3</sup>

NRBC = Nucleated red blood cells/100 WBC's  
Heinz bodies = positive cell/100 RBC's

\*\*Median  
[ ] Quartile deviation

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Table 19  
Mean Results of Coagulation Determinations for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

7-Week Results

<u>Dosage</u>	<u>Prothrombin Time (Seconds)</u>	<u>Partial Thromboplastin Time (Seconds)</u>
MALES		
<u>300 ppm</u>	12.0 (0.5)	18.6 <sup>b</sup> (0.6)
<u>30 ppm</u>	12.8 (1.0)	18.8 <sup>b</sup> (2.3)
<u>3 ppm</u>	12.2 (0.6)	18.4 <sup>b</sup> (1.5)
<u>0 ppm</u>	13.1 (1.9)	21.1 (2.2)
FEMALES		
<u>300 ppm</u>	11.1 (0.7)	15.5 (1.8)
<u>30 ppm</u>	11.4 (1.1)	16.2 (2.1)
<u>3 ppm</u>	11.5 (0.8)	17.0 (2.6)
<u>0 ppm</u>	11.8 (1.0)	17.8 (4.4)

( ) Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01

b = 0.01 > p > 0.001

c = p < 0.001

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Table 20

Mean Results of Coagulation Determinations for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

13-Week Results

<u>Dosage</u>	<u>Prothrombin Time (Seconds)</u>	<u>Partial Thromboplastin Time (Seconds)</u>
MALES		
<u>300 ppm</u>	11.4 (1.2)	17.8 (2.0)
<u>30 ppm</u>	11.6 (1.1)	18.8 (1.8)
<u>3 ppm</u>	11.6 (1.0)	19.5 (2.3)
<u>0 ppm</u>	11.6 (1.1)	19.6 (2.4)
FEMALES		
<u>300 ppm</u>	9.8 (0.9)	16.6 (2.2)
<u>30 ppm</u>	10.3 (1.2)	16.6 (1.2)
<u>3 ppm</u>	10.1 (1.2)	17.7 (2.0)
<u>0 ppm</u>	10.3 (1.0)	18.8 (2.5)

( ) Standard deviation

WPC/rkk/0547B-2  
10-25-84

Table 21

Mean Results of Coagulation Determinations for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 17-Week Results

<u>Dosage</u>	<u>Prothrombin Time (Seconds)</u>	<u>Partial Thromboplastin Time (Seconds)</u>
MALES		
<u>300 ppm</u>	12.1 (0.9)	22.0 (1.9)
<u>0 ppm</u>	11.7 (1.1)	21.1 (2.2)
FEMALES		
<u>300 ppm</u>	11.6 (0.6)	18.6 (1.3)
<u>0 ppm</u>	11.7 (0.8)	18.4 (1.4)
() Standard deviation		

WPC/rkk/0547B-1  
11-09-84

Table 22

Mean Results of Cholinesterase Determinations for CD<sup>®</sup> Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 7-Week Results

<u>Dosage</u>	<u>Plasma</u>	<u>% Inhibition</u>	<u>RBC</u>	<u>% Inhibition</u>
MALES				
<u>300 ppm</u>	0.33 <sup>c</sup> (0.04)	50.7	0.17 <sup>c</sup> (0.02)	91.1
<u>30 ppm</u>	0.49 <sup>b</sup> (0.06)	26.9	0.60 <sup>c</sup> (0.12)	68.8
<u>3 ppm</u>	0.57 (0.11)	14.9	1.72 <sup>b</sup> (0.10)	10.4
<u>0 ppm</u>	0.67 (0.16)		1.92 (0.18)	
FEMALES				
<u>300 ppm</u>	0.64 <sup>c</sup> (0.12)	77.1	0.19 <sup>c</sup> (0.03)	90.7
<u>30 ppm</u>	1.02 <sup>c</sup> (0.18)	63.4	0.53 <sup>c</sup> (0.09)	74.1
<u>3 ppm</u>	1.73 <sup>b</sup> (0.36)	38.0	1.77 <sup>c</sup> (0.08)	13.7
<u>0 ppm</u>	2.79 (1.02)		2.05 (0.17)	

() Standard deviation

Superscript denotes level of significance vs. control:  
 a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

Plasma = Plasma cholinesterase (U/mL)

RBC = Erythrocyte cholinesterase (U/mL)

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Table 23

Mean Results of Cholinesterase Determinations for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 13-Week Results

Dosage	Plasma	% Inhibition	RBC	% Inhibition	Brain	% Inhibition
MALES						
<u>300 ppm</u>	0.35 <sup>c</sup> (0.03)	53.9	0.14 <sup>c</sup> (0.03)	93.1	3.20 <sup>c</sup> (0.43)	26.4
<u>30 ppm</u>	0.52 <sup>b</sup> (0.08)	31.6	0.66 <sup>c</sup> (0.08)	67.5	3.91 (0.57)	10.1
<u>3 ppm</u>	0.62 (0.13)	18.4	1.82 <sup>a</sup> (0.11)	10.3	4.16 (0.59)	4.4
<u>0 ppm</u>	0.76 (0.21)		2.03 (0.24)		4.35 (0.71)	
FEMALES						
<u>300 ppm</u>	0.91 <sup>c</sup> (0.16)	74.7	0.17 <sup>c</sup> (0.03)	91.3	2.32 <sup>c</sup> (0.34)	42.0
<u>30 ppm</u>	1.30 <sup>c</sup> (0.24)	63.8	0.61 <sup>c</sup> (0.16)	68.9	3.61 (0.32)	9.8
<u>3 ppm</u>	2.44 <sup>b</sup> (0.70)	32.0	1.74 <sup>a</sup> (0.20)	11.2	3.89 (0.54)	2.8
<u>0 ppm</u>	3.59 (0.91)		1.96 (0.22)		4.00 (0.66)	

() Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 &gt; p &gt; 0.01; b = 0.01 &gt; p &gt; 0.001; c = p &lt; 0.001

Plasma = Plasma cholinesterase (U/mL)

RBC = Erythrocyte cholinesterase (U/mL)

Brain = Brain cholinesterase (U/mL)

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Table 24

Mean Results of Cholinesterase Determinations for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 17-Week Results

Dosage	Plasma	% Inhibition	RBC	% Inhibition	Brain	% Inhibition
MALES						
300 ppm	0.65 (0.21)	-	1.83 (0.17)	4.2	3.82 (0.15)	8.4
0 ppm	0.61 (0.08)		1.91 (0.18)		4.17 (0.52)	
FEMALES						
300 ppm	3.24 (0.92)	-	1.86 <sup>b</sup> (0.13)	12.3	2.85 <sup>b</sup> (0.46)	17.6
0 ppm	3.23 (0.59)		2.12 (0.19)		3.46 (0.42)	

( ) Standard deviation  
 Superscript denotes level of significance vs. control:

b = 0.01 > p > 0.001

Plasma = Plasma cholinesterase (U/mL)

RBC = Erythrocyte cholinesterase (U/mL)

Brain = Brain cholinesterase (U/mL)

Dash denotes a value either greater than or equal to control.

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Table 25

Mean and Median Results of Clinical Chemistry Parameters for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 7-Week Results

MALES											
Dosage	Gluc*	UN*	AST*	ALT*	TP*	ALB*	Glob*	A/G Ratio*	TB*		
300 ppm	1.02 <sup>b</sup> (0.08)	117 (15)	61 (5)	18 (2)	62 <sup>c</sup> (3)	36 <sup>c</sup> (1)	27 <sup>b</sup> (3)	1.3 (0.2)	4 (1)		
30 ppm	1.18 (0.10)	113 (17)	59 (7)	19 (3)	66 (2)	37 (1)	29 (2)	1.2 (0.1)	4 <sup>a</sup> (1)		
3 ppm	1.16 (0.10)	107 (12)	69 (11)	21 (3)	68 (3)	38 (1)	30 (2)	1.2 (0.1)	3 (1)		
0 ppm	1.14 (0.11)	112 (23)	64 (9)	20 (5)	68 (3)	38 (1)	31 (3)	1.2 (0.1)	3 (1)		

Dosage	CPK*	LDH*	GGT**	Chol*	ALP*	Ca*	P*	Na*	K*	Cl*
300 ppm	108 (47)	113 (67)	0 [0]	0.56 <sup>c</sup> (0.08)	67 (16)	101 (5)	71 (4)	144 (2)	5.3 <sup>b</sup> (0.3)	105 (1)
30 ppm	70 (19)	86 (35)	0 [0]	0.46 (0.09)	81 (16)	102 (3)	70 (5)	144 (1)	5.3 <sup>a</sup> (0.2)	105 <sup>a</sup> (2)
3 ppm	128 (91)	194 (212)	0 [0]	0.44 (0.09)	82 (12)	102 (5)	69 (4)	144 (1)	5.2 (0.3)	105 <sup>a</sup> (2)
0 ppm	145 (137)	174 (149)	0 [0]	0.40 (0.08)	85 (21)	102 (6)	71 (3)	144 (2)	5.0 (0.3)	104 <sup>a</sup> (2)

\*Mean

() Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

Gluc = Glucose (g/L)

UN = Urea nitrogen (mg/L)

AST = Aspartate aminotransferase (U/L)

ALT = Alanine aminotransferase (U/L)

TP = Total protein (g/L)

ALB = Albumin (g/L)

Glob = Globulin (g/L)

A/G Ratio = Albumin + Globulin

TB = Total bilirubin (mg/L)

\*\*Median

[] Quartile deviation

CPK = Creatine phosphokinase (U/L)

LDH = Lactic dehydrogenase (U/L)

GGT =  $\gamma$ -glutamyl transferase (U/L)

Chol = Cholesterol (g/L)

ALP = Alkaline phosphatase (U/L)

Ca = Calcium (mg/L)

P = Inorganic phosphorous (mg/L)

Na = Sodium (mmol/L)

K = Potassium (meq/L)

Cl = Chloride (mmol/L)

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Table 26

Mean and Median Results of Clinical Chemistry Parameters for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 7-Week Results

Dosage	Gluc*	UN*	AST*	ALT*	TP*	ALB*	Glob*	A/G Ratio*	TB*	
FEMALES										
300 ppm	1.01 (0.09)	127 (13)	58 (11)	15 (3)	57 <sup>c</sup> (3)	33 (2)	24 <sup>c</sup> (2)	1.4 <sup>b</sup> (0.1)	5 (1)	
30 ppm	1.02 (0.12)	135 (19)	56 (6)	17 (4)	63 (3)	34 (3)	29 (2)	1.2 (0.2)	5 (1)	
3 ppm	1.06 (0.10)	125 (16)	56 (8)	15 (3)	64 (3)	34 (2)	30 (3)	1.2 (0.1)	5 (1)	
0 ppm	1.07 (0.14)	131 (25)	56 (9)	17 (3)	64 (4)	35 (2)	29 (2)	1.2 (0.1)	4 (1)	
Dosage	CPK*	LDH*	GGT**	Chol*	ALP*	Ca*	P*	Na*	K*	Cl*
300 ppm	138 (83)	87 (26)	0 [0]	0.49 (0.12)	44 (11)	101 (2)	65 (4)	144 (1)	5.4 (0.7)	108 (1)
30 ppm	100 (53)	89 (13)	0 [0]	0.52 (0.06)	44 (12)	103 (3)	62 (9)	144 (1)	5.1 (0.5)	108 (2)
3 ppm	164 (153)	109 (45)	0 [0]	0.49 (0.07)	44 (13)	102 (3)	59 (8)	145 (1)	4.9 (0.5)	108 (1)
0 ppm	130 (57)	108 (25)	0 [0]	0.51 (0.07)	50 (13)	102 (3)	60 (5)	145 (1)	5.1 (0.4)	108 (1)

\*Mean

() Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

Gluc = Glucose (g/L)

UN = Urea nitrogen (mg/L)

AST = Aspartate aminotransferase (U/L)

ALT = Alanine aminotransferase (U/L)

TP = Total protein (g/L)

ALB = Albumin (g/L)

Glob = Globulin (g/L)

A/G Ratio = Albumin ÷ Globulin

TB = Total bilirubin (mg/L)

\*\*Median

[] Quartile deviation

CPK = Creatine phosphokinase (U/L)

LDH = Lactic dehydrogenase (U/L)

GGT =  $\gamma$ -glutamyl transferase (U/L)

Chol = Cholesterol (g/L)

ALP = Alkaline phosphatase (U/L)

Ca = Calcium (mg/L)

P = Inorganic phosphorous (mg/L)

Na = Sodium (mmol/L)

K = Potassium (meq/L)

Cl = Chloride (mmol/L)

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Table 27

Mean and Median Results of Clinical Chemistry Parameters for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 13-Week Results

Dosage	MALES										TB*
	Gluc*	UN*	AST*	ALT*	TP*	ALB*	Glob*	A/G Ratio*	TB*		
<u>300 ppm</u>	1.09 (0.12)	120 (19)	58 (10)	18 (4)	63 <sup>c</sup> (3)	34 <sup>b</sup> (1)	28 <sup>c</sup> (3)	1.2 <sup>c</sup> (0.1)	4 (1)		
<u>30 ppm</u>	1.25 (0.12)	113 (12)	60 (8)	20 (2)	69 (3)	36 (1)	33 (2)	1.1 (0.1)	3 (1)		
<u>3 ppm</u>	1.22 (0.11)	114 (18)	61 (15)	22 (7)	70 (4)	36 (2)	34 (3)	1.0 (0.1)	3 (1)		
<u>0 ppm</u>	1.18 (0.09)	117 (21)	57 (7)	21 (4)	71 (5)	36 (1)	35 (4)	1.0 (0.1)	3 (1)		

Dosage	CPK*	LDH*	GGT**	Chol*	ALP*	CA*	P*	Na*	K*	Cl*
<u>300 ppm</u>	64 (13)	119 (27)	0 [0]	0.85 (0.16)	55 (18)	101 (2)	60 (5)	145 (1)	5.3 (0.5)	108 (1)
<u>30 ppm</u>	108 (111)	132 (39)	0 [0]	0.73 (0.11)	64 (16)	102 (2)	58 (4)	145 (1)	5.3 (0.7)	106 (1)
<u>3 ppm</u>	75 (18)	139 (58)	0 [0]	0.80 (0.20)	69 (16)	102 (3)	55 (6)	146 (1)	5.2 (0.4)	107 (2)
<u>0 ppm</u>	71 (17)	131 (33)	0 [0]	0.75 (0.12)	70 (17)	103 (3)	57 (4)	145 (1)	5.0 (0.4)	107 (1)

\*Mean

() Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

Gluc = Glucose (g/L)

UN = Urea nitrogen (mg/L)

AST = Aspartate aminotransferase (U/L)

ALT = Alanine aminotransferase (U/L)

TP = Total protein (g/L)

ALB = Albumin (g/L)

Glob = Globulin (g/L)

A/G Ratio = Albumin ÷ Globulin

TB = Total bilirubin (mg/L)

\*\*Median

[] Quartile deviation

Chol = Cholesterol (g/L)

ALP = Alkaline phosphatase (U/L)

Ca = Calcium (mg/L)

P = Inorganic phosphorous (mg/L)

Na = Sodium (mmol/L)

K = Potassium (meq/L)

Cl = Chloride (mmol/L)

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Table 28

Mean and Median Results of Clinical Chemistry Parameters for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

13-Week Results

Dosage	Gluc*	UN*	AST*	ALT*	TP*	ALB*	Glob*	A/G Ratio*	TB*	
FEMALES										
300 ppm	1.06 (0.15)	149 (44)	56 (10)	15 <sup>a</sup> (2)	65 <sup>a</sup> (6)	38 (3)	28 <sup>b</sup> (4)	1.4 <sup>b</sup> (0.1)	4 (1)	
30 ppm	1.16 (0.12)	141 (35)	63 (19)	20 (5)	74 (6)	40 (4)	34 (4)	1.2 (0.2)	3 (1)	
3 ppm	1.12 (0.10)	137 (31)	57 (5)	17 (3)	72 (4)	38 (2)	34 (3)	1.2 (0.1)	2 (1)	
0 ppm	1.09 (0.14)	136 (26)	69 (27)	19 (2)	72 (5)	38 (2)	33 (3)	1.2 (0.1)	3 (1)	
Dosage	CPK*	LDH*	GGT**	Chol*	ALP*	Ca*	P*	Na*	K*	Cl*
300 ppm	88 (50)	158 (74)	0 [0]	0.92 (0.24)	34 (13)	100 (2)	53 (8)	143 (2)	5.0 <sup>c</sup> (0.3)	109 (2)
30 ppm	93 (46)	196 (54)	0 [0]	0.99 (0.18)	30 (9)	103 (4)	49 (7)	144 (1)	4.8 (0.2)	109 (2)
3 ppm	93 (16)	178 (51)	0 [0]	0.85 (0.10)	34 (14)	101 (3)	47 (6)	144 (2)	4.6 (0.2)	108 (2)
0 ppm	103 (24)	196 (66)	0 [0]	0.82 (0.22)	42 (13)	101 (3)	49 (9)	144 (1)	4.5 (0.3)	108 (2)

\*Mean

( ) Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01; b = 0.01 > p > 0.001; c = p < 0.001

Gluc = Glucose (g/L)

UN = Urea nitrogen (mg/L)

AST = Aspartate aminotransferase (U/L)

ALT = Alanine aminotransferase (U/L)

TP = Total protein (g/L)

ALB = Albumin (g/L)

Glob = Globulin (g/L)

A/G Ratio = Albumin ÷ Globulin

TB = Total bilirubin (mg/L)

\*\*Median

[] Quartile deviation

CPK = Creatine phosphokinase (U/L)

LDH = Lactic dehydrogenase (U/L)

GGT = γ-glutamyl transferase (U/L)

Chol = Cholesterol (g/L)

ALP = Alkaline phosphatase (U/L)

Ca = Calcium (mg/L)

P = Inorganic phosphorous (mg/L)

Na = Sodium (mmol/L)

K = Potassium (meq/L)

Cl = Chloride (mmol/L)

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Table 29

Mean and Median Results of Clinical Chemistry Parameters for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

17-Week Results

MALES											
Dosage	Gluc*	UN*	AST*	ALT*	TP*	ALB*	Glob*	A/G Ratio*	TB*		
300 ppm	1.11 (0.13)	117 (12)	58 (13)	18 (6)	65 (4)	34 (2)	31 <sup>a</sup> (2)	1.1 <sup>b</sup> (0.1)	4. (1)		
0 ppm	1.11 (0.11)	109 (14)	60 (11)	20 (4)	66 (2)	33 (1)	33 (2)	1.0 (0.1)	4. (1)		
FEMALES											
Dosage	Gluc*	UN*	AST*	ALT*	TP*	ALB*	Glob*	A/G Ratio*	TB*		
300 ppm	0.98 (0.09)	143 (25)	54 (12)	19 (7)	70 (4)	39 (3)	31 (2)	1.2 (0.1)	4. (1)		
0 ppm	0.99 (0.11)	140 (26)	57 (8)	19 (6)	69 (5)	38 (4)	32 (2)	1.2 (0.1)	4. (1)		
Dosage	CPK*	LDH*	GGT**	Chol*	ALP*	CA*	P*	NA*	K*	CL*	
300 ppm	130 (59)	202 (91)	0 [0]	0.89 (0.18)	25 (13)	103 (3)	52 (12)	143 (1)	5.0 (0.4)	106 (2)	
0 ppm	117 (82)	183 (90)	0 [0]	0.87 (0.23)	29 (6)	102 (3)	48 (13)	144 (1)	4.8 (0.4)	108 (2)	

\*Mean

() Standard deviation

Superscript denotes level of significance vs. control:

a = 0.05 > p > 0.01; b = 0.01 > p > 0.001

Gluc = Glucose (g/L)

UN = Urea nitrogen (mg/L)

AST = Aspartate aminotransferase (U/L)

ALT = Alanine aminotransferase (U/L)

TP = Total protein (g/L)

ALB = Albumin (g/L)

Glob = Globulin (g/L)

A/G Ratio = Albumin ÷ Globulin

TB = Total bilirubin (mg/L)

\*\*Median

[] Quartile deviation

CPK = Creatine phosphokinase (U/L)

LDH = Lactic dehydrogenase (U/L)

GGT =  $\gamma$ -glutamyl transferase (U/L)

Chol = Cholesterol (g/L)

ALP = Alkaline phosphatase (U/L)

Ca = Calcium (mg/L)

P = Inorganic phosphorous (mg/L)

Na = Sodium (mmol/L)

K = Potassium (meq/L)

Cl = Chloride (mmol/L)

Table 30

**Mean and Median Results for Urinalysis Determinations for CD• Rats**  
**UC 70480 Ninety-Day Dietary Inclusion Study in Rats**

## 6-Week Results

Dosage	Specific Gravity*	pH*	Total Volume* (ml)	Color	Turbidity	MALES			FEMALES		
						Protein** mg/dl	Glucose** g/dl	Ketone** mg/dl	Bilirubin** Blood (Erhlich U/dl)	Bilirubin** Urobilinogen** (Ehrlich U/dl)	
300 ppm	1.039 (0.008)	7 (0)	19.7 (3.5)	lt.yellow	sl.cloudy	30 [0]	0 [0]	5 [0]	0 [0]	0 [0]	
30 ppm	1.046 (0.009)	7 (0)	16.8 (4.1)	yellow	mod.cloudy	30 [0]	0 [0]	15 [0]	0 [0]	0 [0]	
3 ppm	1.044 (0.010)	7 (0)	17.9 (5.2)	lt.yellow	clear	30 [0]	0 [0]	15 [0]	0 [0]	1 [0]	
0 ppm	1.043 (0.009)	7 (0)	18.8 (4.8)	lt.yellow	mod.cloudy	30 [0]	0 [0]	15 [5]	0 [0]	0 [0]	
300 ppm	1.048 (0.009)	7 (0)	11.8 (2.8)	yellow	mod.cloudy	30 [0]	0 [0]	0 [2]	0 [0]	0 [0]	
30 ppm	1.044 (0.011)	7 (0)	13.6 (4.1)	yellow	mod.cloudy	Tr [0]	0 [0]	0 [0]	0 [0]	0 [0]	
3 ppm	1.042 (0.011)	7 (0)	12.8 (3.7)	yellow	mod.cloudy	30 [14]	0 [0]	0 [2]	0 [0]	0 [0]	
0 ppm	1.039 (0.008)	7 (0)	15.6 (4.0)	lt.yellow	mod.cloudy	30 [14]	0 [0]	0 [0]	0 [0]	1 [0]	

\*Mean  
 () Standard deviation  
 Tr = Trace

\*\*Median

[] Quartile deviation

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Report 49

Table 31

Results of Urine Microscopics for Male and Female CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

Dosage	Red Blood Cell	White Blood Cell	Epithelial Cell	Triple Phosphate	Calcium Oxalate	Uric Acid	Amorphous Phosphate	Sperm	Casts	Bacteria	Debris	6-Week Results	
												MALES	FEMALES
300 ppm	none	none	none	few	none	none	none	few	none	none	moderate	few	
30 ppm	none	none	none	few	none	none	none	few	none	none	many	moderate	
3 ppm	none	none	none	few	none	none	none	few	none	none	moderate	few	
0 ppm	none	none	none	few	none	none	none	none	moderate	none	many	moderate	
300 ppm	none	none	none	few	none	none	none	none	moderate	none	many	few	
30 ppm	none	none	none	few	none	none	none	NA	none	few	few	few	
3 ppm	none	none	none	few	none	none	none	NA	none	few	few	few	
0 ppm	none	none	none	few	none	none	none	NA	none	NA	many	moderate	
NA = Not applicable													

Table 32

**Mean and Median Results for Urinalysis Determinations for CD• Rats**  
**UC 70480 Ninety-Day Dietary Inclusion Study in Rats**

## 12-Week Results

Dosage	Specific Gravity*	pH*	Total Volume*	Color	Turbidity	MALES			FEMALES		
						Protein** mg/dl	Glucose** g/dl	Ketone** mg/dl	Urobilinogen** mg/dl	Bilirubin** mg/dl	Blood** (Erlich) U/dl
300 ppm	1.031 (0.007)	7 (0)	21.0 (4.5)	yellow	mod.cloudy	30 [0]	0 [0]	5 [0]	0 [0]	0 [0]	0.1 [0]
30 ppm	1.041 (0.007)	7 (0)	17.4 (4.7)	yellow	mod.cloudy	30 [0]	0 [0]	5 [5]	0 [0]	0 [0]	0.1 [0]
93 ppm of	1.038 (0.009)	7 (0)	18.0 (4.3)	yellow	mod. cloudy	30 [0]	0 [0]	5 [5]	0 [0]	0 [0]	0.1 [0]
67 ppm	1.039 (0.012)	7 (0)	18.4 (3.5)	yellow	mod.cloudy	30 [0]	0 [0]	5 [5]	0 [0]	0 [0]	0.1 [0]
300 ppm	1.042 (0.009)	7 (0)	12.0 (3.3)	yellow	mod.cloudy	30 [14]	0 [0]	0 [0]	0 [0]	0 [0]	0.1 [0]
30 ppm	1.041 (0.016)	7 (0)	13.8 (5.2)	yellow	mod.cloudy	Tr [0]	0 [0]	0 [0]	0 [0]	0 [0]	0.1 [0]
3 ppm	1.029 (0.007)	7 (0)	16.9 (5.1)	yellow	mod.cloudy	Tr [0]	0 [0]	0 [0]	0 [0]	0 [0]	0.1 [0]
0 ppm	1.037 (0.012)	7 (0)	14.8 (9.5)	yellow	mod.cloudy	30 [14]	0 [0]	0 [0]	0 [0]	0 [0]	0.1 [0]

\*Mean  
 () Standard deviation  
 Tr = Trace

\*\*Median  
 [ ] Quartile deviation

Table 33

**Results of Urine Microscopics for Male and Female CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats**

**12-Week Results**

<u>Dosage</u>	<u>Red Blood Cell</u>	<u>White Blood Cell</u>	<u>Epithelial Cell</u>	<u>Triple Phosphate</u>	<u>Calcium Oxalate</u>	<u>Uric Acid</u>	<u>Amorphous Phosphate</u>	<u>Sperm</u>	<u>Casts</u>	<u>Bacteria</u>	<u>Debris</u>
<b>MALES</b>											
<u>300 ppm</u>	none	none	none	few	none	none	none	few	none	packed	few
<u>30 ppm</u>	none	none	none	few	none	none	none	few	none	packed	few
<u>3 ppm</u>	none	none	none	few	none	none	none	few	none	packed	few
<u>0 ppm</u>	none	none	none	few	none	none	none	few	none	packed	few
<b>FEMALES</b>											
<u>300 ppm</u>	none	none	none	few	none	none	none	NA	none	moderate	few
<u>30 ppm</u>	none	none	none	none	none	none	none	NA	none	few	few
<u>3 ppm</u>	none	none	none	few	none	none	none	NA	none	packed	few
<u>0 ppm</u>	none	none	none	few	none	none	none	NA	none	few	few

NA = Not applicable

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Table 34

Mean and Median Results for Urinalysis Determinations for CD® Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 16-Week Results

Dosage	Specific Gravity*	pH*	Volume† (ml)	Color	Turbidity	Total		Protein**		Glucose**		Ketone**		Urobilinogen**	
						mg/dl	g/dl	mg/dl	mg/dl	mg/dl	g/dl	mg/dl	g/dl	mg/dl	g/dl
<b>MALES</b>															
300 ppm	1.046 (0.010)	7 (0)	14.0 (4.0)	yellow	mod.cloudy	65 [35]	0 [0]	15 [5]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0.1 [0]	0.1 [0]
0 ppm	1.047 (0.013)	7 (0)	14.2 (5.6)	yellow	mod.cloudy	65 [35]	0 [0]	5 [5]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0.1 [0]	0.1 [0]
<b>FEMALES</b>															
300 ppm	1.048 (0.017)	7 (0)	14.6 (5.0)	yellow	sl.cloudy	30 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	1 [0]
0 ppm	1.045 (0.012)	7 (0)	14.8 (5.6)	yellow	sl.cloudy	30 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	1 [0]	1 [0]

\*Mean  
( ) Standard deviation  
† Quartile deviation  
\*\*Median

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Table 35

Results of Urine Microscopics for Male and Female CD• Rats  
UC 70480 Ninety-Day Dietary Inclusion Study in Rats

## 16-Week Results

Dosage	Red Blood Cell	White Blood Cell	Epithelial Cell	Triple Phosphate	Calcium Oxalate	Uric Acid	Amorphous Phosphate	Sperm	Casts	Bacteria	Debris
MALES											
300 ppm	none	none	none	few	none	none	none	few	none	moderate	few
0 ppm	none	none	none	none	none	none	none	moderate	none	moderate	few
FEMALES											
300 ppm	none	none	none	none	none	none	none	NA	none	few	moderate
0 ppm	none	none	none	none	none	none	none	NA	none	few	moderate

NA = Not applicable

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TABLE 36  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 13-WEEK SACRIFICE  
MALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
BRAIN	2.033	0.0803	20	2.096	0.0623	20	2.085	0.1125	20	2.076	0.1033	20
LIVER	12.908	1.8714	20	13.536	1.6058	20	13.155	2.1735	20	13.013	1.5651	20
KIDNEY	3.105	0.3380	20	3.109	0.2574	20	3.118	0.3904	20	2.926	0.2772	20
SPLEEN	0.712	0.1161	20	0.745	0.1235	20	0.771	0.1777	20	0.760	0.1317	20
HEART	1.342	0.1154	20	1.359	0.1146	20	1.343	0.1600	20	1.217**	0.1340	20

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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Report 49

TABLE 36 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 13-WEEK SACRIFICE

GROUP (PPM):	0	3	30	300
ADRENAL GLANDS				
MEAN	0.0711	0.0698	0.0740	0.0717
S.D.	0.01558	0.01347	0.01758	0.01759
N	20	20	20	20
TESTES				
MEAN	3.484	3.503	3.359	3.320
S.D.	0.2952	0.2802	0.3642	0.2655
N	20	20	20	20

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 37  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 13-WEEK SACRIFICE  
MALES

GROUP (PPM):	3			30			300		
	0	20	20	0	20	20	0	20	20
BRAIN	MEAN S.D. N	0.448 0.0260 20		0.437 0.0302 20		0.444 0.0439 20		0.480** 0.0427 20	
LIVER	MEAN S.D. N	2.834 0.3462 20		2.809 0.2445 20		2.770 0.2744 20		2.994 0.2560 20	
KIDNEY	MEAN S.D. N	0.684 0.0748 20		0.646 0.0391 20		0.659 0.0498 20		0.674 0.0478 20	
SPLEEN	MEAN S.D. N	0.157 0.0248 20		0.155 0.0232 20		0.162 0.0280 20		0.175 0.0294 20	
HEART	MEAN S.D. N	0.295 0.0241 20		0.283 0.0208 20		0.284 0.0132 20		0.280 0.0246 20	

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 37 (continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 13-WEEK SACRIFICE  
 MALES

GROUP (PPM):	0			3			30			300		
	ADRENAL GLANDS	TESTES	None									
	MEAN	0.016	0.015	MEAN	0.016	0.017	MEAN	0.016	0.017	MEAN	0.016	0.017
	S.D.	0.0033	0.0030	S.D.	0.0030	0.0029	S.D.	0.0029	0.0048	S.D.	0.0029	0.0048
	N	20	20									
	MEAN	0.768	0.729	MEAN	0.716	0.768	MEAN	0.716	0.768	MEAN	0.716	0.768
	S.D.	0.0730	0.0567	S.D.	0.1002	0.0795	S.D.	0.1002	0.0795	S.D.	0.1002	0.0795
	N	20	20									

None significantly different from control group

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TABLE 3B  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 13-WEEK SACRIFICE  
MALES

GROUP (PPM):				0	3	30	300
LIVER	MEAN	635.387	646.362	630.737	628.389		
	S.D.	93.7589	77.8294	98.4459	84.1224		
	N	20	20	20	20		
KIDNEY	MEAN	152.817	148.453	149.511	141.192		
	S.D.	16.7731	12.9894	16.9404	14.4616		
	N	20	20	20	20		
SPLEEN	MEAN	35.065	35.646	37.017	36.773		
	S.D.	5.8203	6.3408	8.8462	7.0694		
	N	20	20	20	20		
HEART	MEAN	66.108	64.905	64.447	58.701**		
	S.D.	6.1254	5.7441	7.5420	6.6619		
	N	20	20	20	20		
ADRENAL GLANDS	MEAN	3.487	3.333	3.551	3.452		
	S.D.	0.6975	0.6426	0.7889	0.8070		
	N	20	20	20	20		

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 38 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 13-WEEK SACRIFICE  
MALES

GROUP (PPM) :	0	3	30	300
TESTES				
MEAN	171.627	167.325	161.681	160.009
S.D.	16.2326	15.0068	20.1134	11.5692
N	20	20	20	20

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 39  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FINAL BODY WEIGHTS (G), SUMMARY OF MEANS AT 13-WEEK SACRIFICE  
MALES

GROUP (PPM):	0	3	30	300
FINAL BODY WT	454.8	481.1**	473.8	434.7
MEAN	27.21	26.15	55.13	35.04
S.D.				
N	20	20	20	20

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 40  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 17-WEEK SACRIFICE  
MALES

GROUP (PPM):	0		3		30		300	
	BRAIN							
	MEAN	2.111	0.000	0.000	0.000	0.000	2.062	
	S.D.	0.0646	0.0000	0.0000	0.0000	0.0000	0.0975	
	N	10	0	0	0	0	10	
LIVER	MEAN	13.486	0.000	0.000	0.000	0.000	15.099	
	S.D.	1.6915	0.0000	0.0000	0.0000	0.0000	2.5456	
	N	10	0	0	0	0	10	
KIDNEY	MEAN	3.139	0.000	0.000	0.000	0.000	3.165	
	S.D.	0.2512	0.0000	0.0000	0.0000	0.0000	0.3054	
	N	10	0	0	0	0	10	
SPLEEN	MEAN	0.778	0.000	0.000	0.000	0.000	0.761	
	S.D.	0.1061	0.0000	0.0000	0.0000	0.0000	0.0847	
	N	10	0	0	0	0	10	
HEART	MEAN	1.387	0.000	0.000	0.000	0.000	1.363	
	S.D.	0.1548	0.0000	0.0000	0.0000	0.0000	0.1223	
	N	10	0	0	0	0	10	

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 40 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 17-WEEK SACRIFICE

MALES			
GROUP (PPM):	0	3	30
ADRENAL GLANDS			
MEAN	0.0588	0.0000	0.0000
S.D.	0.00942	0.00000	0.00000
N	10	0	0
TESTES			
MEAN	3.419	0.000	0.000
S.D.	0.3293	0.0000	0.0000
N	10	0	0

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 41  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 17-WEEK SACRIFICE  
MALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
BRAIN	0.420	0.0363	10	0.000	0.0000	0	0.000	0.0000	0	0.412	0.0445	10
LIVER	2.665	0.2543	10	0.000	0.0000	0	0.000	0.0000	0	2.987*	0.4010	10
KIDNEY	0.621	0.0353	10	0.000	0.0000	0	0.000	0.0000	0	0.630	0.0648	10
SPLEEN	0.153	0.0130	10	0.000	0.0000	0	0.000	0.0000	0	0.151	0.0114	10
HEART	0.274	0.0208	10	0.000	0.0000	0	0.000	0.0000	0	0.270	0.0061	10

\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.05 LEVEL

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TABLE 41 (Continued)  
 UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 17-WEEK SACRIFICE  
 MALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
ADRENAL GLANDS	0.012	0.0021	10	0.0000	0.0000	0	0.000	0.0000	0	0.012	0.0019	10
TESTES	0.676	0.0497	10	0.0000	0.0000	0	0.000	0.0000	0	0.679	0.0633	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 42  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 17-WEEK SACRIFICE  
MALES

GROUP (PPM):	LIVER			KIDNEY			SPLEEN			HEART			ADRENAL GLANDS		
	0	3	30	0	3	30	0	3	30	0	3	30	0	3	30
LIVER	MEAN S.D. N	630.661 76.6983 10	0.000 0.0000 0												
KIDNEY	MEAN S.D. N	148.643 10.1845 10	0.000 0.0000 0												
SPLEEN	MEAN S.D. N	36.855 4.9559 10	0.000 0.0000 0												
HEART	MEAN S.D. N	65.665 6.7384 10	0.000 0.0000 0												
ADRENAL GLANDS	MEAN S.D. N	2.779 0.4093 10	0.000 0.0000 0												

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 42 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 17-WEEK SACRIFICE  
MALES

GROUP (PPM):		0	3	30	300
TESTES	MEAN	161.888	0.000	0.000	165.123
	S.D.	13.8800	0.0000	0.0000	9.3255
	N	10	0	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 43  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FINAL BODY WEIGHTS (G), SUMMARY OF MEANS AT 17-WEEK SACRIFICE  
MALES

GROUP (PPM):	0	3	30	300
FINAL BODY WT	MEAN	506.7	0.0	504.4
	S.D.	52.04	0.00	46.82
	N	10	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 44  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N									
BRAIN	1.933	0.0769	19	1.961	0.0886	20	1.945	0.0766	19	1.915	0.0896	18
LIVER	7.072	0.7684	19	7.001	0.8823	20	7.343	0.9147	19	7.611	1.0130	18
KIDNEY	1.904	0.1259	19	1.895	0.1462	20	1.920	0.1528	19	1.872	0.1728	18
SPLEEN	0.499	0.2061	19	0.440	0.0702	20	0.529	0.0677	19	0.526	0.0681	18
HEART	0.844	0.0694	19	0.862	0.0870	20	0.912	0.0865	19	0.863	0.0902	18

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 44 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
<b>ADRENAL GLANDS</b>				
MEAN	0.0886	0.0913	0.0862	0.0787
S.D.	0.02080	0.01944	0.01642	0.01680
N	19	20	19	18
<b>OVARIES</b>				
MEAN	0.1585	0.1845	0.1540	0.1511
S.D.	0.05547	0.04580	0.05922	0.04676
N	19	20	19	18

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 45  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
BRAIN				
MEAN	0.747	0.756	0.731	0.761
S.D.	0.0534	0.0779	0.0650	0.0774
N	19	20	19	18
LIVER				
MEAN	2.722	2.680	2.742	2.997**
S.D.	0.1918	0.2484	0.2217	0.2111
N	19	20	19	18
KIDNEY				
MEAN	0.736	0.729	0.721	0.741
S.D.	0.0639	0.0727	0.0655	0.0661
N	19	20	19	18
SPLEEN				
MEAN	0.193	0.169	0.199	0.208
S.D.	0.0817	0.0283	0.0263	0.0204
N	19	20	19	18
HEART				
MEAN	0.326	0.331	0.342	0.340
S.D.	0.0251	0.0297	0.0280	0.0213
N	19	20	19	18

\*\* = SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP AT 0.01 LEVEL

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TABLE 45 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):		0	3	30	300
ADRENAL GLANDS					
MEAN	0.034	0.035	0.032	0.031	
S.D.	0.0089	0.0073	0.0071	0.0076	
N	19	20	19	18	
OVARIES					
MEAN	0.061	0.071	0.058	0.060	
S.D.	0.0206	0.0180	0.0226	0.0182	
N	19	20	19	18	

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 46  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N									
LIVER	366.210	39.9267	19	357.177	42.7898	20	376.249	50.3289	19	399.278	65.1781	18
KIDNEY	98.524	5.6033	19	96.830	8.3685	20	98.884	9.1820	19	98.115	11.9464	18
SPLEEN	25.770	9.9149	19	22.511	3.8945	20	27.214	3.3913	19	27.706	4.4670	18
HEART	43.746	4.0891	19	43.994	4.0915	20	46.962	4.6710	19	45.178	5.6844	18
ADRENAL GLANDS	4.589	1.1018	19	4.646	0.8999	20	4.441	0.8777	19	4.136	1.0727	18

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 46 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	OVARIES	0			3			30			300		
		MEAN	S.D.	N									
		8.224	2.8917	19	9.403	2.2505	20	7.918	3.0261	19	7.916	2.5296	18

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 47  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FINAL BODY WEIGHTS (G), SUMMARY OF MEANS AT 13-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
FINAL BODY WT	259.8	261.9	267.6	253.4
MEAN	19.75	30.34	23.54	21.52
S.D.		20	19	18
N	19			

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 48  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
BRAIN	MEAN S.D. N	1.910 0.0808 10	0.000 0.0000 0	0.000 0.0000 0
LIVER	MEAN S.D. N	8.141 1.0258 10	0.000 0.0000 0	1.955 0.0980 10
KIDNEY	MEAN S.D. N	1.994 0.1524 10	0.000 0.0000 0	8.652 1.0196 10
SPLEEN	MEAN S.D. N	0.499 0.0953 10	0.000 0.0000 0	2.005 0.1060 10
HEART	MEAN S.D. N	0.952 0.1175 10	0.000 0.0000 0	0.546 0.0833 10
NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP				

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TABLE 48 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS (G). SUMMARY OF MEANS AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
ADRENAL GLANDS				
MEAN	0.0754	0.0000	0.0000	0.0732
S.D.	0.00884	0.00000	0.00000	0.01125
N	10	0	0	10
OVARIES				
MEAN	0.1606	0.0000	0.0000	0.1275
S.D.	0.04459	0.00000	0.00000	0.03460
N	10	0	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 49  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300	
BRAIN	MEAN S.D. N	0.689 0.0602 10	0.000 0.0000 0	0.000 0.0000 0	0.693 0.0550 10
LIVER	MEAN S.D. N	2.920 0.2658 10	0.000 0.0000 0	0.000 0.0000 0	3.049 0.2161 10
KIDNEY	MEAN S.D. N	0.717 0.0426 10	0.000 0.0000 0	0.000 0.0000 0	0.193 0.0319 10
SPLEEN	MEAN S.D. N	0.179 0.0334 10	0.000 0.0000 0	0.000 0.0000 0	0.710 0.0376 10
HEART	MEAN S.D. N	0.342 0.0298 10	0.000 0.0000 0	0.000 0.0000 0	0.340 0.0170 10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 49 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % FINAL BODY WEIGHT AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0			3			30			300		
	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N	MEAN	S.D.	N
ADRENAL GLANDS	0.027	0.0038	10	0.000	0.0000	0	0.000	0.0000	0	0.026	0.0040	10
OVARIES	0.058	0.0188	10	0.000	0.0000	0	0.000	0.0000	0	0.045	0.0129	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 50  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM) :		0	3	30	300
LIVER					
MEAN	427.027	0	0.000	0.000	442.880
S.D.	58.3015	0	0.0000	0.0000	52.1273
N	10	0	0	0	10
KIDNEY					
MEAN	104.456	0	0.000	0.000	102.617
S.D.	8.0151	0	0.0000	0.0000	4.5492
N	10	0	0	0	10
SPLEEN					
MEAN	26.184	0	0.000	0.000	27.917
S.D.	5.2050	0	0.0000	0.0000	4.2449
N	10	0	0	0	10
HEART					
MEAN	49.802	0	0.000	0.000	49.367
S.D.	5.3850	0	0.0000	0.0000	4.6034
N	10	0	0	0	10
ADRENAL GLANDS					
MEAN	3.942	0	0.000	0.000	3.756
S.D.	0.38880	0	0.0000	0.0000	0.6284
N	10	0	0	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 50 (Continued)  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
ORGAN WEIGHTS AS % BRAIN WEIGHT AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
OVARIES	8.400 2.2825 10	0.000 0.0000 0	0.000 0.0000 0	6.537 1.8755 10
MEAN	8.400	0.000	0.000	6.537
S.D.	2.2825	0.0000	0.0000	1.8755
N	10	0	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 51  
UC 70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
FINAL BODY WEIGHTS (G). SUMMARY OF MEANS AT 17-WEEK SACRIFICE  
FEMALES

GROUP (PPM):	0	3	30	300
FINAL BODY WT				
MEAN	278.7	0.0	0.0	283.0
S.D.	23.98	0.00	0.00	16.68
N	10	0	0	10

NONE SIGNIFICANTLY DIFFERENT FROM CONTROL GROUP

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TABLE 52  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
GROSS NECKOPSY OBSERVATIONS - INCIDENCE SUMMARY

	GROUP:	MALE			
		1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)		20	20	20	20
EYES/OPTIC N.		1	0	0	0
-CLOUDY		1	0	0	0
-MISSHAPEN					
KIDNEY		3	1	0	1
-HYDRONEPHROSIS		0	0	0	1
-COLOR CHANGE					
LUNG/BRONCHI		0	0	1	1
-COLOR CHANGE					
NOSE/TURRINATES		0	0	1	0
-ENCrustation					
PANCREAS		0	1	0	0
-CYST					
LYMPH NODE,CERV.					
-SIZE CHANGE					
1-GROUP P (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30 PPM)    4-GROUP Y (300PPM)		1	1	0	0

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TABLE 53  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
GROSS NEUROPSY OBSERVATIONS - INCIDENCE SUMMARY

NUMBER OF ANIMALS IN DOSE GROUP	NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)	F E M A L E				
		GROUP:	1	2	3	4
EYES/OPTIC N.			1	0	0	0
-OPACITY						
KIDNEY			2	2	3	0
-HYDONEPHROSIS						
LYMPH NODE, RE.			0	1	0	0
-COLOR CHANGE						
OVARIES			0	1	0	0
-CYST (S)						
SPLEEN			1	0	0	0
-SIZE CHANGE						
THYMUS GLAND			1	0	0	0
-SIZE CHANGE						
UTERUS			1	1	0	0
-SIZE CHANGE						
LYMPH NODE, CERV.			1	0	1	0
-SIZE CHANGE						
-COLOR CHANGE			1	0	1	0
1-GROUP F (0 FPM)	2-GROUP S (3 FPM)	3-GROUP T (30PPM)	4-GROUP Y (300PPM)			

TABLE 54  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
SACRIFICED DURING KILL 1(WEEK 13)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)	20	20	20	20
ADRENAL GLANDS	20	0	0	20
TOTAL NUMBER EXAMINED	18	0	0	16
EXAMINED, UNREMARKABLE	2	0	0	4
-CORTICAL VACUOLAR CHANGE				
ANUS/RECTUM	20	0	0	20
TOTAL NUMBER EXAMINED	18	0	0	20
EXAMINED, UNREMARKABLE	2	0	0	0
-NEMATODIASIS				
BRAIN	20	0	0	20
TOTAL NUMBER EXAMINED	20	0	0	20
EXAMINED, UNREMARKABLE				
CECUM	20	0	0	20
TOTAL NUMBER EXAMINED	18	0	0	19
EXAMINED, UNREMARKABLE	0	0	0	1
-SEROSAL GRANULOMA	2	0	0	0
-NEMATODIASIS				
COLON	20	0	0	19
TOTAL NUMBER EXAMINED	19	0	0	19
EXAMINED, UNREMARKABLE	0	0	0	1
NOT EXAMINED	1	0	0	0
-NEMATODIASIS				

1-GROUP F (0 FPM) 2-GROUP S (3 FPM) 3-GROUP T (30 FPM) 4-GROUP Y (300 FPM)

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Table 54 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

		MALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP						
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)		30	20	20	30	
DUODENUM						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		20	0	0	0	20
EPITHELIOMYOSIS						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		19	0	0	0	20
-EPITHELIOMYOSIS		1	0	0	0	0
EYES/OPTIC N.						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		19	0	0	0	20
-CATARACT		1	0	0	0	0
-CORNEAL VASCULARIZATION		1	0	0	0	0
-KERATITIS		1	0	0	0	0
-CONJUNCTIVITIS		1	0	0	0	0
HEART						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		18	0	0	0	17
-EFICARDITIS		0	0	0	0	1
-MYOCARDITIS		0	0	0	0	0
1-GROUP F (0 FFM) 2-GROUP S (30 FFM) 3-GROUP T (300 FFM) 4-GROUP U (3000 FFM)						3

Table 54 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)	20	20	20	20
ILEUM	20	0	0	20
TOTAL NUMBER EXAMINED	20	0	0	20
EXAMINED, UNREMARKABLE	20	0	0	20
KIDNEY	9	14	12	13
TOTAL NUMBER EXAMINED	9	14	12	13
EXAMINED, UNREMARKABLE	8	5	8	6
-INTERSTITIAL NEFROITIS	0	0	0	1
-TUBULAR HYALIN DROPLET DEGENERATION	0	2	1	1
-TUBULAR CELL HYPERPLASIA	5	0	0	0
-CAPILLARY HYPERPLASIA	1	0	0	0
-PELVIC MINERALIZATION	1	0	0	0
-UROLITHIASIS	3	1	0	0
-HYDRONEPHROSIS	1	0	0	0
-MINERALIZATION	0	0	1	0
-INTERSTITIAL FIBROSIS	0	0	0	0
LIVER	20	20	20	20
TOTAL NUMBER EXAMINED	6	5	7	8
EXAMINED, UNREMARKABLE	9	11	10	10
-LYMPHOID FOCI	1	3	6	2
-EXTRAMEDULLARY HEMATOPOIESIS	2	3	2	1
-HEPATOCELLULAR DEGENERATION	5	3	1	0
-CHOLANGITIS	0	0	0	0
1-GROUP P (0 PPM)      2-GROUP S (3 PPM)      3-GROUP T (30 PPM)      4-GROUP Y (300 PPM)				

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Table 54 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP				
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)	30	20	20	30
-HEPATITIS	20	20	20	20
-VACUOLAR DEGENERATION	4	0	0	0
LYMPH NODE, ME.				
TOTAL NUMBER EXAMINED	19	0	0	20
NOT EXAMINED	1	0	0	0
-SINUS ERYTHROCYTOSIS	2	0	0	0
-SINUS HISTIOCYTOSIS	19	0	0	1
-HEMOSIDEROSIS	0	0	0	19
-LYMPHOID HYPERPLASIA	8	0	0	1
-LYMPHATIC ECTASIA	6	0	0	5
-GRANULOMA	1	0	0	2
-PLASMACYTOSIS	1	0	0	0
LUNG/BRONCHI				
TOTAL NUMBER EXAMINED	20	20	20	20
EXAMINED, UNREMARKABLE	18	15	16	15
-ALVEOLAR HISTIOCYTOSIS	0	1	0	5
-MINERALIZATION	1	0	0	0
-FERNKONCHIOLAR LYMPHOID HYPERPLASIA	1	2	1	0
-GRANULOMA	0	0	1	0
-ATELECTASIS	0	0	3	0
-FERIVASCULAR LYMPHOID CUFFS	0	0	0	1
-HEMORRHAGE	0	0	0	0
-INTERSTITIAL PNEUMONIA, GRANULOMATOUS	0	0	0	0
1-GROUP P (0 PPM) 2-GROUP S (3 PPM)	0	0	0	0

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Table 54 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

		MALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)			20	20	20	20
-SUBMUCOSAL LYMPHOID HYPERPLASIA			1	0	0	0
MAMMARY GLAND						
TOTAL NUMBER EXAMINED			12	0	0	14
EXAMINED, UNREMARKABLE			12	0	0	14
NOT EXAMINED			0	0	0	0
PANCREAS						
TOTAL NUMBER EXAMINED			20	1	0	20
EXAMINED, UNREMARKABLE			16	0	0	19
-PANCREATITIS			3	0	0	1
-ACINAR CELL ATROPHY			1	0	0	0
-SEROSAL CYST			0	1	0	0
-SEROSITIS			0	1	0	0
PITUITARY						
TOTAL NUMBER EXAMINED			20	0	0	19
EXAMINED, UNREMARKABLE			20	0	0	16
NOT EXAMINED			0	0	0	1
-CYST(S)			0	0	0	3
FROSTATE						
TOTAL NUMBER EXAMINED			20	0	0	20
EXAMINED, UNREMARKABLE			20	0	0	19
-PROSTATITIS			0	0	0	1
1-GROUP P (0 FFM)    2-GROUP S (3 FFM)    3-GROUP T (30 FFM)    4-GROUP Y (300 FFM)						

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Table 54 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS - SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

		MALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP						
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)		30	20	20	30	30
		20	20	20	20	20
SALIVARY GLANDS						
TOTAL NUMBER EXAMINED		20	1	0	0	20
EXAMINED, UNREMARKABLE		15	1	0	0	19
-FATTY INFILTRATION		5	0	0	0	0
-SIALOADENITIS		1	0	0	0	1
SKIN						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		13	0	0	0	18
-HYPERKERATOSIS		4	0	0	0	2
-ACANTHOSIS		6	0	0	0	0
SPINAL CORD						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		20	0	0	0	18
-VACUOLAR DEGENERATION		0	0	0	0	2
SPLEEN						
TOTAL NUMBER EXAMINED		20	0	0	0	20
EXAMINED, UNREMARKABLE		10	0	0	0	18
-HEMOSIDEROSIS		10	0	0	0	18
-SEROSITIS		1	0	0	0	2
-EXTRAMEDULLARY HEMATOPOEISIS		2	0	0	0	0
-LYMFHOID NECROSIS		1	0	0	0	0

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Table 54 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1 (WEEK 13)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1 (WEEK 13)	20	20	20	20
THYMUS GLAND				
TOTAL NUMBER EXAMINED	19	0	0	20
EXAMINED, UNREMARKABLE	16	0	0	20
NOT EXAMINED	1	0	0	0
-PHYSIOLOGIC ATROPHY	3	0	0	0
THYROID GLAND				
TOTAL NUMBER EXAMINED	20	0	0	20
EXAMINED, UNREMARKABLE	16	0	0	17
-THYROGLOSSAL DUCT CYST(S)	4	0	0	3
TRACHEA				
TOTAL NUMBER EXAMINED	20	0	0	20
EXAMINED, UNREMARKABLE	19	0	0	19
-TRACHEITIS	1	0	0	1
URINARY BLADDER				
TOTAL NUMBER EXAMINED	20	0	0	20
EXAMINED, UNREMARKABLE				
-LYMPHOID HYPERPLASIA				
LYMPH NODE, CERV.				
TOTAL NUMBER EXAMINED	20	1	0	20
EXAMINED, UNREMARKABLE	0	0	0	2
-LYMPHOID HYPERPLASIA	15	1	0	14

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Table 54 (Continued)  
**UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS**  
**HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE**  
**SACRIFICED DURING KILL 1(WEEK 13)**

		<b>MALE</b>		
		<b>GROUP:</b>	<b>1</b>	<b>2</b>
<b>NUMBER OF ANIMALS IN DOSE GROUP</b>		30	20	20
<b>NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)</b>		20	20	20
<b>-SINUS HISTIOCYTOSIS</b>		16	1	0
<b>-PLASMACYTOSIS</b>		15	1	0
<b>-LYMPHATIC ECTASIA</b>		5	0	0
<b>PREPUTIAL GLAND</b>				
<b>TOTAL NUMBER EXAMINED</b>		1	0	0
<b>-ABSCESS</b>		1	0	0
<b>1-GROUP P (0 PPM)</b>	<b>2-GROUP S (3 PPM)</b>	<b>3-GROUP T (30 PPM)</b>	<b>4-GROUP Y (300PPM)</b>	

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TABLE 55  
UC70490 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
SACRIFICED DURING KILL 1(WEEK 13)

----- FEMALE -----

	GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)		19	20	19	18
ADRENAL GLANDS		19	0	0	18
TOTAL NUMBER EXAMINED		19	0	0	18
EXAMINED, UNREMARKABLE		18	0	0	16
ANUS/RECTUM		19	0	0	16
TOTAL NUMBER EXAMINED		18	0	0	16
EXAMINED, UNREMARKABLE		0	0	0	2
NOT EXAMINED		1	0	0	0
-SURMUCOSAL LYMPHOID INFILTRATE(S)		1	0	0	0
CULON		19	0	0	18
TOTAL NUMBER EXAMINED		19	0	0	18
EXAMINED, UNREMARKABLE		18	0	0	18
DUODENUM		19	0	0	17
TOTAL NUMBER EXAMINED		18	0	0	17
EXAMINED, UNREMARKABLE		0	0	0	1
NOT EXAMINED		1	0	0	0
-FLASHACYTIC ENTERITIS		1	0	0	0
EYES/OPTIC N.		19	0	0	18
TOTAL NUMBER EXAMINED		19	0	0	17
EXAMINED, UNREMARKABLE		19	0	0	17
-CORNEAL VASCULARIZATION		0	0	0	1
1-GROUP P (0 FFM)    2-GROUP S (3 FPM)    3-GROUP T (300PPM)    4-GROUP Y (3000PPM)					

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Table 55 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN NOSE GROUP			30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)			19	20	19	18
HEART						
TOTAL NUMBER EXAMINED		19	0	0	0	18
EXAMINED, UNREMARKABLE		19	0	0	0	18
ILEUM						
TOTAL NUMBER EXAMINED		19	0	0	0	17
EXAMINED, UNREMARKABLE		19	0	0	0	17
NOT EXAMINED		0	0	0	0	1
JEJUNUM						
TOTAL NUMBER EXAMINED		19	0	0	0	17
EXAMINED, UNREMARKABLE		19	0	0	0	17
NOT EXAMINED		0	0	0	0	1
KIDNEY						
TOTAL NUMBER EXAMINED		19	20	19	19	18
EXAMINED, UNREMARKABLE		13	9	16	16	13
-MINERALIZATION		1	3	0	0	2
-HYDRONEPHROSIS		4	3	3	3	3
-HELVIC CALCULI		0	0	0	0	2
-INTERSTITIAL NEPHRITIS		3	5	2	2	0
-TUBULAR ECSTASIA		0	1	0	0	0
-SUFFLUVATIVE NEPHRITIS		1	0	0	0	0

1-GROUP P (0 PPM) 2-GROUP S (3 PPM) 3-GROUP T (30PPM) & 4-GROUP X (300PPM)

Table 55 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)			19	20	19	18
LIVER						
TOTAL NUMBER EXAMINED		19	20	19	18	
EXAMINED, UNREMARKABLE		6	5	8	7	
-CHOLANGITIS		2	9	5	4	
-LYMPHOID FOCI		8	13	10	10	
-HEPATITIS		0	0	0	1	
-HEPATOCELLULAR VACUOLATION		0	0	1	0	
-HEPATOCELLULAR DEGENERATION		0	0	1	0	
-EXTRAMEDULLARY HEPATOPOIESIS		5	0	0	0	
LYMPH NODE, ME.						
TOTAL NUMBER EXAMINED		19	0	0	18	
EXAMINED, UNREMARKABLE		2	0	0	4	
-LYMPHATIC ECTASIA		6	0	0	4	
-LYMPHOID HYPERPLASIA		19	0	0	18	
-SINUS HISTIOCYTOSIS		1	0	0	1	
-SINUS ERYTHROCYTOSIS		2	0	0	3	
-PLASMACYTOSIS						
LUNG/BRONCHI						
TOTAL NUMBER EXAMINED		19	20	19	18	
EXAMINED, UNREMARKABLE		18	15	17	18	
-ALVEOLAR HISTIOCYTOSIS		0	2	0	0	
-HEMORRHAGE		0	1	0	0	
-ATELACTASIS		0	1	2	0	

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Table 55 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

	FEMALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)	19	20	19	18
-LYMPHOID HYPERPLASIA	0	1	2	0
-FM LYMPHORLASTIC LYMPHOMA	1	0	0	0
OVARIES				
TOTAL NUMBER EXAMINED	19	2	0	18
EXAMINED, UNREMARKABLE	18	1	0	18
-EPITHELIAL CYST	0	1	0	0
-FOLLICULAR CYST(S)	1	0	0	0
PANCREAS				
TOTAL NUMBER EXAMINED	19	0	0	17
EXAMINED, UNREMARKABLE	18	0	0	17
NOT EXAMINED	0	0	0	1
-PANCREATITIS	1	0	0	0
SALIVARY GLANDS				
TOTAL NUMBER EXAMINED	19	0	0	18
EXAMINED, UNREMARKABLE	18	0	0	18
-SUFFLUVIATE SIALOADENITIS	1	0	0	0
SKIN				
TOTAL NUMBER EXAMINED	19	0	0	18
EXAMINED, UNREMARKABLE	19	0	0	15
-ACANTHOSIS	0	0	0	3

1-GROUP P (0 FFM) 2-GROUP S (3 PPM) 3-GROUP T (30PPM)

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Table 55 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)			19	20	19	18
SPINAL CORD						18
TOTAL NUMBER EXAMINED			19	0	0	18
EXAMINED, UNREMARKABLE			19	0	0	17
-VACUOLIZATION			0	0	0	1
SPLEEN						18
TOTAL NUMBER EXAMINED			19	0	0	18
EXAMINED, UNREMARKABLE			8	0	0	9
-HEMOSIDEROSIS			8	0	0	8
-EXTRAMEDULLARY HEMATOPOEISIS			4	0	0	2
-IM LYMPHORBLASTIC LYMPHOMA			1	0	0	0
THYMUS GLAND						18
TOTAL NUMBER EXAMINED			19	0	0	18
EXAMINED, UNREMARKABLE			18	0	0	18
-IM LYMPHORBLASTIC LYMPHOMA			1	0	0	0
THYROID GLAND						18
TOTAL NUMBER EXAMINED			19	0	0	18
EXAMINED, UNREMARKABLE			16	0	0	14
-THYROGLOSSAL DUCT CYST(S)			2	0	0	4
-THYROIDITIS			1	0	0	0
1-GROUP F (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30PPM)    4-GROUP Y (300PPM)						
† = NEOPLASM, M = MALIGNANT						

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Table 55 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 1(WEEK 13)

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP				
NUMBER OF ANIMALS SACRIFICED DURING KILL 1(WEEK 13)	30	20	20	30
	19	20	19	18
URINARY BLADDER				
TOTAL NUMBER EXAMINED	18	0	0	18
EXAMINED, UNREMARKABLE	18	0	0	18
NOT EXAMINED	1	0	0	0
UTERUS				
TOTAL NUMBER EXAMINED	19	1	0	17
EXAMINED, UNREMARKABLE	13	0	0	14
NOT EXAMINED	0	0	0	1
-LUMINAL ECTASIA, UNILATERAL	2	0	0	2
-LUMINAL ECTASIA, BILATERAL	4	1	0	1
LYMPH NODE, CERV.				
TOTAL NUMBER EXAMINED	19	0	3	18
-SINUS HISTIOCYTOSIS	19	0	3	18
-LYMPHATIC ECTASIA	4	0	0	4
-LYMPHOID HYPERPLASIA	16	0	3	16
-PLASMACYTOSIS	14	0	2	16
-SINUS ERYTHROCYTOSIS	2	0	1	2
-HEMOSIDEROSIS	0	0	0	1
HARTERIAN GLAND				
TOTAL NUMBER EXAMINED	5	0	0	7
EXAMINED, UNREMARKABLE	5	0	0	6
-GLANULAR ECTASIA	0	0	0	0

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Table 56  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
GROSS NECROPSY OBSERVATIONS - INCIDENCE SUMMARY

	FEMALE			
	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS FOUND DEAD OR SACRIFICED MORIBUND	1	0	1	2
LUNG/BRONCHI				
-COLOR CHANGE	1	0	0	2
1-GROUP P (0 FPM)	1			
2-GROUP S (3 FPM)				
3-GROUP T (30FFM)				
4-GROUP Y (300PPM)				

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TABLE 57  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
FOUND DEAD OR SACRIFICED MORIBUND

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS FOUND DEAD OR SACRIFICED MORIBUND			1	0	1	2
ANTRAL GLANDS						
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		1	0	1	2	
ANUS/RECTUM						
TOTAL NUMBER EXAMINED		1	0	1	1	
EXAMINED, UNREMARKABLE		1	0	1	1	
NOT EXAMINED		0	0	0	1	
COLON						
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		1	0	1	2	
AUDIENUM						
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		1	0	1	2	
EYES/OPTIC N.						
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		1	0	1	2	
HEART						
TOTAL NUMBER EXAMINED		1	0	1	2	

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Table 57 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 FOUND DEAD OR SACRIFICED MORIBUND

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30	
NUMBER OF ANIMALS FOUND DEAD OR SACRIFICED MORIBUND		1	0	1	2	
ILEUM						2
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		0	0	0	0	
-AUTOLYSIS		1	0	0	0	
JEJUNUM						2
TOTAL NUMBER EXAMINED		1	0	1	1	
EXAMINED, UNREMARKABLE		0	0	0	0	
-AUTOLYSIS		1	0	1	1	
KIDNEY						2
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		0	0	0	0	
-MINERALIZATION		1	0	0	0	
LIVER						2
TOTAL NUMBER EXAMINED		1	0	1	2	
EXAMINED, UNREMARKABLE		0	0	0	0	
-LYMPHOID FOCI		1	0	1	1	
LYMPH NODE, ME.		1	0	1	2	
TOTAL NUMBER EXAMINED		1	0	1	1	
-LYMPHOID HYPERPLASIA		1	0	1	1	
-SINUS HISTIOCYTOSIS		1	0	1	2	
1-GROUP P (0 FPM)	2-GROUP S (3 FPM)	3-GROUP T (30 FPM)	4-GROUP Y (300 FPM)			

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Table 57 (Continued)  
 UC70480 NINETY-RAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 FOUND DEAD OR SACRIFICED MORIBUND

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS FOUND DEAD OR SACRIFICED MORIBUND			1	0	1	2
LUNG/BRONCHI						
TOTAL NUMBER EXAMINED			1	0	1	2
-CONGESTION			1	0	1	2
OVARIES						
TOTAL NUMBER EXAMINED			1	0	1	2
EXAMINED, UNREMARKABLE			1	0	1	2
PANCREAS						
TOTAL NUMBER EXAMINED			1	0	1	2
EXAMINED, UNREMARKABLE			1	0	1	2
SALIVARY GLANDS						
TOTAL NUMBER EXAMINED			1	0	1	2
EXAMINED, UNREMARKABLE			1	0	1	2
SKIN						
TOTAL NUMBER EXAMINED			0	0	1	2
EXAMINED, UNREMARKABLE			0	0	1	2
NOT EXAMINED			1	0	0	0
SPIINAL CORD						
TOTAL NUMBER EXAMINED			1	0	1	2
EXAMINED, UNREMARKABLE			1	0	1	2

1-GROUP P (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (50PPM)    4-GROUP V (300PPM)

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Table 57 (Continued)

UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 FOUND DEAD OR SACRIFICED MORIBUND

----- FEMALE -----

	GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30
NUMBER OF ANIMALS FOUND DEAD OR SACRIFICED MORIBUND		1	0	1	2
SPLEEN					
TOTAL NUMBER EXAMINED		1	0	1	2
EXAMINED, UNREMARKABLE		0	0	1	1
-HEMOSIDEROSIS		1	0	0	0
-LYMPHOID NECROSIS		0	0	0	1
-LYMPHOID HYPERPLASIA		0	0	0	1
THYMUS GLAND					
TOTAL NUMBER EXAMINED		1	0	1	2
EXAMINED, UNREMARKABLE		1	0	1	2
THYROID GLAND					
TOTAL NUMBER EXAMINED		1	0	1	2
EXAMINED, UNREMARKABLE		1	0	1	1
-AUTOLYSIS		0	0	0	1
URINARY BLADDER					
TOTAL NUMBER EXAMINED		1	0	1	2
EXAMINED, UNREMARKABLE		1	0	1	2
UTERUS					
TOTAL NUMBER EXAMINED		1	0	1	2
EXAMINED, UNREMARKABLE		1	0	1	2
1-GROUP P (0 PPM)	2-GROUP S (3 PPM)	3-GROUP T (30PPM)	4-GROUP Y (300PPM)		

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Table 57 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 FOUND DEAD OR SACRIFICED MORIBUND

FEMALE				
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS FOUND DEAD OR SACRIFICED MORIBUND	1	0	1	2
LYMPH NODE, CERV.				
TOTAL NUMBER EXAMINED	1	0	0	0
NOT EXAMINED	0	0	1	2
-SINUS HISTIOCYTOSIS	1	0	0	0
-LYMFHOID HYPERPLASIA	1	0	0	2
-FLASMACYTOSIS	1	0	0	0
HARNERIAN GLAND				
TOTAL NUMBER EXAMINED	1	0	1	2
EXAMINED, UNREMARKABLE	1	0	1	2
1-GROUP P (0 PPM)				
2-GROUP S (3 PPM)				
3-GROUP T (30PPM)				
4-GROUP Y (300PPM)				

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Table 58  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
GROSS NECKOPSY OBSERVATIONS - INCIDENCE SUMMARY

	GROUP:	MALE			
		1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)		10	0	0	10
EYES/OPTIC N.		1	0	0	0
-COLOR CHANGE		0	0	0	1
-HEMORRHAGE					
KIDNEY		1	0	0	2
-HYDRONEPHROSIS					
SEMINAL VESICLE		1	0	0	0
-SIZE CHANGE					
LYMPH NODE, CERV.		2	0	0	0
-SIZE CHANGE		1	0	0	0
-COLOR CHANGE					
1-GROUP P (0 FPM)	2-GROUP S (3 FPM)	3-GROUP T (30 FPM)	4-GROUP Y (300 FPM)		

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TABLE 59  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
GROSS NECKOPSY OBSERVATIONS - INCIDENCE SUMMARY

	NUMBER OF ANIMALS IN NOSE GROUP	FEMALE			
		1	2	3	4
	NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)	30	20	20	30
		10	0	0	10
DUODENUM					
-COLOR CHANGE		0	0	0	1
ILEUM		0	0	0	1
-COLOR CHANGE		0	0	0	1
JEJUNUM		0	0	0	1
-COLOR CHANGE		0	0	0	1
KIDNEY		1	0	0	0
-HYDRONEPHROSIS		2	0	0	0
OVARIES		1	0	0	0
-CYST (S)					
UTERUS					
-SIZE CHANGE					
1-GROUP P (0 PPM)	2-GROUP S (3 PPM)	3-GROUP T (30PPM)	4-GROUP Y (300PPM)		

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TABLE 60  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
SACRIFICED DURING KILL 2(WEEK 17)

		MALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30	
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)		10	0	0	10	
ADRENAL GLANDS						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	0	10
ANUS/RECTUM						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	0	10
BRAIN						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	0	10
-WHITE MATTER VACUOLATION OF CEREBELLUM		0	0	0	0	0
CECUM						
TOTAL NUMBER EXAMINED		9	0	0	0	10
EXAMINED, UNREMARKABLE		9	0	0	0	10
NOT EXAMINED		1	0	0	0	0
COLON						
TOTAL NUMBER EXAMINED		9	0	0	0	10
EXAMINED, UNREMARKABLE		7	0	0	0	10
NOT EXAMINED		1	0	0	0	0
-NEMATODIASIS		2	0	0	0	0
1-GROUP F (0 PPM)	2-GROUP S (3 PPM)	3-GROUP T (30 PPM)	4-GROUP Y (300 PPM)			

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Table 60 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 2(WEEK 17)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP				
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)	30	20	20	30
	10	0	0	10
DUODENUM				
TOTAL NUMBER EXAMINED	10	0	0	10
EXAMINED, UNREMARKABLE	9	0	0	10
-LYMPHOID HYPERPLASIA	1	0	0	0
EPIDIDYMIS				
TOTAL NUMBER EXAMINED	10	0	0	10
EXAMINED, UNREMARKABLE	10	0	0	10
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	10	0	0	10
EXAMINED, UNREMARKABLE	9	0	0	9
-CATARACT	1	0	0	1
-KERATITIS	1	0	0	0
-ANTERIOR SYNECHIA	1	0	0	1
-VITREOUS HEMORRHAGE	0	0	0	1
-CHRONIC FIBROSIS OF CILIARY BODY	0	0	0	1
-INTRAOCULAR HEMORRHAGE	0	0	0	1
-FETALINA DETACHMENT	1	0	0	0
-POSTERIOR SYNECHIA	1	0	0	0
HEART				
TOTAL NUMBER EXAMINED	10	0	0	10
EXAMINED, UNREMARKABLE	9	0	0	0

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Table 60 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 2 (WEEK 17)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN NOSE GROUP	30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 2 (WEEK 17)	10	0	0	10
-MYOCARDIAL DEGENERATION	1	0	0	0
ILEUM	10	0	0	10
TOTAL NUMBER EXAMINED	7	0	0	9
EXAMINED, UNREMARKABLE	3	0	0	1
-LYMPHOID HYPERPLASIA	1	0	0	0
-ENTERITIS				
KIDNEY	10	0	0	10
TOTAL NUMBER EXAMINED	4	0	0	3
EXAMINED, UNREMARKABLE	4	0	0	5
-INTERSTITIAL NEPHRITIS	0	0	0	3
-TUBULAR CELL HYPERPLASIA	1	0	0	2
-HYPERONFROSIS	1	0	0	0
-MINERALIZATION	0	0	0	1
-PYELITIS	1	0	0	0
-CYST(S)				
LIVER	10	0	0	10
TOTAL NUMBER EXAMINED	1	0	0	2
EXAMINED, UNREMARKABLE	5	0	0	8
-LYMPHOID FOCI	5	0	0	0
-EXTRAMEDULLARY HEMATOPOIESIS	1	0	0	1
-HEPATOCELLULAR REGENERATION	0	0	0	3
-CHOLANGITIS				
1-GROUP F (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30 PPM)    4-GROUP Y (300PPM)				

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Table 60 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 2(WEEK 17)

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN NOSE GROUP				
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)	30	20	20	30
-HEPATITIS	10	0	0	10
LYMPH NODE, ME.				
TOTAL NUMBER EXAMINED	10	0	0	10
-SINUS ERYTHROCYTOSIS	0	0	0	3
-SINUS HISTIOCYTOSIS	10	0	0	10
-LYMFHOID HYPERPLASIA	3	0	0	1
-LYMFHATIC ECTASIA	0	0	0	2
-FLASMACYTOSIS	2	0	0	1
LUNG/BRONCHI				
TOTAL NUMBER EXAMINED	10	0	0	10
EXAMINED, UNREMARKABLE	10	0	0	7
-PERIBRONCHIAL LYMPHOID HYPERPLASIA	0	0	0	2
-FOREIGN MATERIAL	0	0	0	1
MAMMARY GLAND				
TOTAL NUMBER EXAMINED	7	0	0	8
EXAMINED, UNREMARKABLE	6	0	0	8
NOT EXAMINED	3	0	0	2
-HYPERPLASIA	1	0	0	0
PANCREAS				
TOTAL NUMBER EXAMINED	10	0	0	10
EXAMINED, UNREMARKABLE	5	0	0	5
-PANCREATITIS	5	0	0	5

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Table 60 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 2(WEEK 17)

		MALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)			10	0	0	10
-ACINAR CELL ATROPHY		1	0	0	0	0
-DUCT FIBROSIS		0	0	0	0	2
-LORULAR ATROPHY		0	0	0	0	1
-ISLET CELL HYPERPLASIA		0	0	0	0	1
-HEMOSIDEROSIS		0	0	0	0	1
-PANCREATIC DUCT SCLEROSIS		0	0	0	0	1
-PANCREATIC DUCT ADENITIS		0	0	0	0	1
-ACINAR FIBROSIS		2	0	0	0	0
PITUITARY						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNMARKABLE		10	0	0	0	10
PROSTATE						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNMARKABLE		9	0	0	0	9
-PROSTATITIS		1	0	0	0	1
SALIVARY GLANDS						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNMARKABLE		10	0	0	0	10
SKIN						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNMARKABLE		10	0	0	0	9
-HYPERKERATOSIS		0	0	0	0	1
1-GROUP P (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30 PPM)    4-GROUP Y (300PPM)						

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Table 60 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 2(WEEK 17)

		MALE					
		GROUP:	1	2	3	4	
NUMBER OF ANIMALS IN DOSE GROUP							
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)		30	20	20	30		
-ACANTHOSIS		10	0	0	10		
SPINAL CORD		0	0	0	1		
TOTAL NUMBER EXAMINED		10	0	0	10		
EXAMINED, UNREMARKABLE		10	0	0	10		
SPLEEN		0	0	0	0		
TOTAL NUMBER EXAMINED		10	0	0	10		
EXAMINED, UNREMARKABLE		1	0	0	0		
-HEMOSIDEROSIS		1	0	0	0		
-EXTRAMEDULLARY HEMATOPOEISIS		9	0	0	7		
THYMUS GLAND		4	0	0	7		
TOTAL NUMBER EXAMINED		9	0	0	10		
EXAMINED, UNREMARKABLE		6	0	0	9		
NOT EXAMINED		3	0	0	0		
-PHYSIOLOGIC ATROPHY		1	0	0	0		
-HEMORRHAGE		1	0	0	0		
-LYMPHOID HYPERPLASIA		0	0	0	0		
-SINUS ERYTHROCYTOSIS		2	0	0	1		
THYROID GLAND		1	0	0	0		
TOTAL NUMBER EXAMINED		10	0	0	10		
EXAMINED, UNREMARKABLE		10	0	0	10		
-THYROIDAL MULI CYST(S)		0	0	0	0		

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Table 60 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 SACRIFICED DURING KILL 2(WEEK 17)

		MALE			
GROUP:		1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30
NUMBER OF ANIMALS SACRIFICED DURING KILL 2(WEEK 17)		10	0	0	10
TRACHEA	TOTAL NUMBER EXAMINED	10	0	0	10
	EXAMINED, UNREMARKABLE	10	0	0	10
URINARY BLADDER	TOTAL NUMBER EXAMINED	10	0	0	10
	EXAMINED, UNREMARKABLE	10	0	0	9
	-FOLLICULAR CYSTITIS	0	0	0	1
LYMPH NODE, CERV.	TOTAL NUMBER EXAMINED	10	0	0	9
	NOT EXAMINED	0	0	0	1
-LYMPHOID HYPERPLASIA		8	0	0	5
-SINUS HISTIOCYTOSIS		5	0	0	9
-PLASMACYTOSIS		8	0	0	6
-LYMPHATIC ECSTASIA		0	0	0	1
-CONGESTION		0	0	0	1
-SINUS ERYTHROCYTOSIS		1	0	0	0
LYMPH NODE, PAN.	TOTAL NUMBER EXAMINED	1	0	0	0
	-SINUS ERYTHROCYTOSIS	1	0	0	0
-HEMOSIDEROSIS		1	0	0	0
1-GROUP F (0 PPM)	2-GROUP S (3 PPM)	3-GROUP T (30 PPM)	4-GROUP Y (300 PPM)		

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TABLE 61  
UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
AT RISK FOR KILL 2(WEEK 17)

		FEMALE				
		GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30
NUMBER OF ANIMALS AT RISK FOR KILL 2(WEEK 17)			10	0	0	10
ADRENAL GLANDS						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		9	0	0	0	9
-CORTICAL NODULAR HYPERPLASIA		1	0	0	0	1
ANUS/RECTUM						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		9	0	0	0	10
-NEMATODIASIS		1	0	0	0	0
COLON						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		8	0	0	0	10
-NEMATODIASIS		2	0	0	0	0
DUODENUM						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	0	10
EYES/OPTIC N.						
TOTAL NUMBER EXAMINED		10	0	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	0	10

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Table 61 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS - SUMMARY INCIDENCE  
 AT RISK FOR KILL 2(WEEK 17)

		FEMALE					
		GROUP:	1	2	3	4	
NUMBER OF ANIMALS IN DOSE GROUP			30	20	20	30	
NUMBER OF ANIMALS AT RISK FOR KILL 2(WEEK 17)			10	0	0	10	
HEART							
TOTAL NUMBER EXAMINED		10	0	0	0	10	
EXAMINED, UNREMARKABLE		10	0	0	0	9	
-FAPILLARY MUSCLE FIBROSIS		0	0	0	0	1	
ILEUM							
TOTAL NUMBER EXAMINED		10	0	0	0	10	
EXAMINED, UNREMARKABLE		10	0	0	0	7	
-LYMPHOID HYPERPLASIA		0	0	0	0	3	
JEJUNUM							
TOTAL NUMBER EXAMINED		10	0	0	0	10	
EXAMINED, UNREMARKABLE		10	0	0	0	9	
-CONGESTION		0	0	0	0	1	
KIDNEY							
TOTAL NUMBER EXAMINED		10	0	0	0	10	
EXAMINED, UNREMARKABLE		7	0	0	0	8	
-MINERALIZATION		2	0	0	0	1	
-HYDRONEPHROSIS		1	0	0	0	1	
-INTERSTITIAL NEPHRITIS		1	0	0	0	0	
1-GROUP P (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30PPM)    4-GROUP Y (300PPM)							

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Table 61 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 AT RISK FOR KILL 2(WEEK 17)

----- FEMALE -----

		GROUP:			
		1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP		30	20	20	30
NUMBER OF ANIMALS AT RISK FOR KILL 2(WEEK 17)		10	0	0	10
<b>LIVER</b>					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		1	0	0	4
-CHOLANGITIS		4	0	0	2
-LYMPHOID FOCI		6	0	0	5
-HEPATITIS		1	0	0	0
<b>LYMPH NODE, ME.</b>					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		1	0	0	0
-LYMPHATIC ECTASIA		1	0	0	4
-LYMPHOID HYPERPLASIA		10	0	0	9
-SINUS HISTIOCYTOSIS		0	0	0	1
-SINUS ERYTHROCYTOSIS		0	0	0	0
-HEMOSIDEROSIS		0	0	0	0
<b>LUNG/BRONCHI</b>					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		9	0	0	7
-LYMPHOID HYPERPLASIA OF BRONCHI		1	0	0	0
-ALVEOLAK HISTIOCYTOSIS		0	0	0	3
<b>OVARIES</b>					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	10
1-GROUP P (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30PPM)    4-GROUP Y (300PPM)					

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Table 61 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 AT RISK FOR KILL 2(WEEK 17)

----- FEMALE -----

	GROUP:	1	2	3	4
NUMBER OF ANIMALS IN NOSE GROUP					
NUMBER OF ANIMALS AT RISK FOR KILL 2(WEEK 17)	30	20	20	30	
	10	0	0	10	
PANCREAS					
TOTAL NUMBER EXAMINED	10	0	0	10	
EXAMINED, UNREMARKABLE	8	0	0	10	
-ACINAR DEGENERATION	1	0	0	0	
-FATTY INFILTRATION	1	0	0	0	
SALIVARY GLANDS					
TOTAL NUMBER EXAMINED	10	0	0	10	
EXAMINED, UNREMARKABLE	10	0	0	10	
SKIN					
TOTAL NUMBER EXAMINED	10	0	0	10	
EXAMINED, UNREMARKABLE	10	0	0	10	
SPINAL CORD					
TOTAL NUMBER EXAMINED	10	0	0	10	
EXAMINED, UNREMARKABLE	10	0	0	10	
SPLEEN					
TOTAL NUMBER EXAMINED	10	0	0	10	
-HEMOSIDEROSIS	10	0	0	10	
-EXTRAMEDULLARY HEMATOPOIESIS	1	0	0	6	
1-GROUP P (0 PPM)    2-GROUP S (3 PPM)    3-GROUP T (30PPM)    4-GROUP Y (300PPM)					

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Table 61 (Continued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 AT RISK FOR KILL 2(WEEK 17)  
 FEMALE -----

	GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP					
NUMBER OF ANIMALS AT RISK FOR KILL 2(WEEK 17)		30	20	20	30
		10	0	0	10
THYMUS GLAND					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	10
THYROID GLAND					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		6	0	0	7
-THYROGLOSSAL NUCT CYST(S)		4	0	0	3
URINARY BLADDER					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		10	0	0	9
-FOLLICULAR CYSTITIS		0	0	0	1
UTERUS					
TOTAL NUMBER EXAMINED		10	0	0	10
EXAMINED, UNREMARKABLE		7	0	0	8
-LUMINAL ECTASIA, UNILATERAL		2	0	0	2
-LUMINAL ECTASIA, BILATERAL		1	0	0	0
LYMPH NODE, CERV.					
TOTAL NUMBER EXAMINED		10	0	0	9
NOT EXAMINED		0	0	0	1
-SINUS HISTIOTCYTOSIS					
1-GROUP P (0 PPM)    2-GROUP S: (3 PPM)    3-GROUP T: (30 PPM)					

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Table 61 (Cont'dued)  
 UC70480 NINETY-DAY DIETARY INCLUSION STUDY IN RATS  
 HISTOMORPHOLOGICAL DIAGNOSIS -- SUMMARY INCIDENCE  
 AT RISK FOR KILL 2(WEEK 17)

----- FEMALE -----

	GROUP: 1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	30	20	20	30
NUMBER OF ANIMALS AT RISK FOR KILL 2(WEEK 17)	10	0	0	10
-LYMPHATIC ECTASIA	1	0	0	0
-LYMPHOID HYPERPLASIA	10	0	0	8
-PLASMACYTOSIS	10	0	0	7
HARDERIAN GLAND	0	0	0	5
TOTAL NUMBER EXAMINED	0	0	0	5
EXAMINED, UNREMARKABLE				
OVINDUCT	2	0	0	0
TOTAL NUMBER EXAMINED	2	0	0	0
-CYSTIC OVINDUCT				
1-GROUP P (0 PPM)	2-GROUP S (3 PPM)	3-GROUP T (30PPM)	4-GROUP Y (300PPM)	

**BUSHY RUN RESEARCH CENTER**

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Telephone (412) 733-5200

Quality Assurance Unit Study Inspection Summary

Test Substance: UC 70480

Study: Ninety-Day Dietary Inclusion in Rats

Study Director: J. P. Van Miller, Ph.D.

The Quality Assurance Unit of BRRC conducted the inspections listed below and reported the results to the study director and to management on the dates indicated. It is the practice of this Quality Assurance Unit to report the results of each inspection to both the study director and management.

<u>Date</u>	<u>Inspection</u>	<u>Type</u>	<u>Date QAU Report Issued</u>	
			<u>To Study Director</u>	<u>To Management</u>
6-21-84		Protocol	6-21-84	6-25-84
7-3-84		Event - Start of Dosing	7-3-84	9-13-84
8-13-84		Event - Clinical Chemistry, Hematology, and CHE	8-13-84	9-13-84
8-21-84		Protocol Amendment 1	8-21-84	8-23-84
9-27-84		Event - Urinalysis	9-28-84	11-28-84
10-4-84		Event - Cholinesterase, Hematology, Clinical Chemistry, and Necropsy	10-4-84	11-28-84
10-23-84		Event - Urinalysis	10-23-84	11-28-84
10-29-84		Event - Necropsy, CHE, Clinical Chemistry, and Hematology	11-2-84	11-28-84
2-7 to 2-11-85		Analytical Raw Data and Report	2-14-85	2-15-85
2-18- to 2-20-85		Raw Data and Report Tables	3-26-85	8-19-86
3-15 to 3-25-85		Clinical Pathology Raw Data and Report	3-26-85	4-9-85

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Report 49-11

<u>Date</u>	<u>Inspection</u>	<u>Type</u>	<u>Date QAU Report Issued</u>	
			<u>To Study Director</u>	<u>To Management</u>
-3 to 4-30-85		Anatomic Pathology Raw Data and Report	4-30-85	5-28-85
-19-85		Protocol Amendment 2	4-19-85	5-1-85
-3-85		Protocol Amendment 3	6-3-85	6-4-85
-4-85		Protocol Amendment 4	9-6-85	9-10-85
-4 to 8-19-86		Final Report	8-19-86	1-13-87
1-19-86		Archives	11-20-86	1-13-87

*Linda J. Calisti* 1-13-87  
Linda J. Calisti, Group Leader      Date  
Good Laboratory Practices/  
Quality Assurance

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

William C. Kuryla, Ph.D.  
Associate Director, Product Safety  
Union Carbide Corporation  
39 Old Ridgebury Road  
Danbury, Connecticut 06817-0001

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., SEHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

*Terry R. O'Bryan*  
Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

12131A



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## Triage of 8(e) Submissions

Date sent to triage: \_\_\_\_\_

NON-CAP

CAP

Submission number: 12131A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO                  AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX                  SBTOX                  SEN                  w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX                  CTOX                  EPI                  RTOX                  GTOX  
STOX/ONCO                  CTOX/ONCO                  IMMUNO                  CYTO                  NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

For Contractor Use Only

entire document: 0 1 2 pages 1,2

pages 1-3, tab

Notes:

Contractor reviewer : LPS

Date: 2/16/95

## CECATS DATA TRACKING DBASE ENTRY FORM

CECATS DATA  
Submission # 8EHO-0992-12131

SEQ. A

TYPE SUPPL FLWP

SUBMITTER NAME:

Unilever Carbide Corporation

SUB. DATE: 08/20/92 ONS DATE: 09/01/92

CSRAD DATE: 01/31/95

CHEMICAL NAME:

Phosphorothioate, (O-(1-cyano-2-methylpropyl)-O-ethyl-S-propyl-

UC 70480

- DISPOSITION:  
 REFER TO CHEMICAL SCREENING  
 CAP NOTICE

INFORMATION REQUESTED: FLWP DATE:

- 6501 NO INFO REQUESTED  
 6502 INFO REQUESTED (TECH)  
 6503 INFO REQUESTED (VOL ACTIONS)  
 6504 INFO REQUESTED (REPORTING RATIONALE)

OPTIONAL ACTIONS:  
 STUDIES/STANDARDS  
 NOTIFICATION IN WORKING MANNER  
 LABEL/MSDS (BLANKS)  
 PROCESSIONAL INDICATIONS  
 AP/AUSE DISCONTINUED  
 PRODUCTION DISCONTINUED  
 CONFIDENTIAL

INFORMATION TYPE:

LFC

INFORMATION TYPE:

LFC

INFORMATION TYPE:

LFC

0201	ONCO (HUMAN)	01 02 04	0216	EPICLIN	01 02 04	0241	IMMUNO (ANIMAL)
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEMPHYS PROP
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)
0205	MUTA (IN VIVO)	01 02 04	0220	BCOMQUA TOX	01 02 04	0245	CLASTO (ANIMAL)
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV OCCUREL/FATE	01 02 04	0246	CLASTO (HUMAN)
0207	REPROTERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQUEST DELAY	01 02 04	0248	PRODUSE/PROC
0209	NEURO (ANIMAL)	01 02 04	0224	PRODCOMPAC/HM ID	01 02 04	0251	MSDS
0210	ACUTE TOX (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0252	OTHER
0211	CHR. TOX (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04		
0212	ACUTE TOX (ANIMAL)	01 02 04	0227	ALLRG (HUMAN)	01 02 04		
0213	SUB ACUTE TOX (ANIMAL)	01 02 04	0228	ALLRG (ANIMAL)	01 02 04		
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0229	KETAPAPHARMACO (ANIMAL)	01 02 04		
0215	CHRONIC TOX (ANIMAL)	01 02 04	0230	KETAPAPHARMACO (HUMAN)	01 02 04		

INVENTORY

NON-CBL INVENTORY

ONGOING REVIEW

SPECIES

TOXICOLOGICAL CONCERN:

PRODUCTION:

CAS SR

(IN NUMBER)

YES

YES (DROP/REFER)

RAT

LOW

NO

NO (CONTINUE)

MED

REFR

HIGH

RESULTS: Rat (LSD) 200 ppm, 1st dietary combination of 1,3,3-D and 3,3'-OBP in the potassium bromate diet. Inhibition of cholinesterase activity (100% after 1 hour, 50% after 2 hours). Inhibition of cholinesterase activity (100% after 1 hour, 50% after 2 hours).

The NOAEL was 3 ppm, in the Ames.